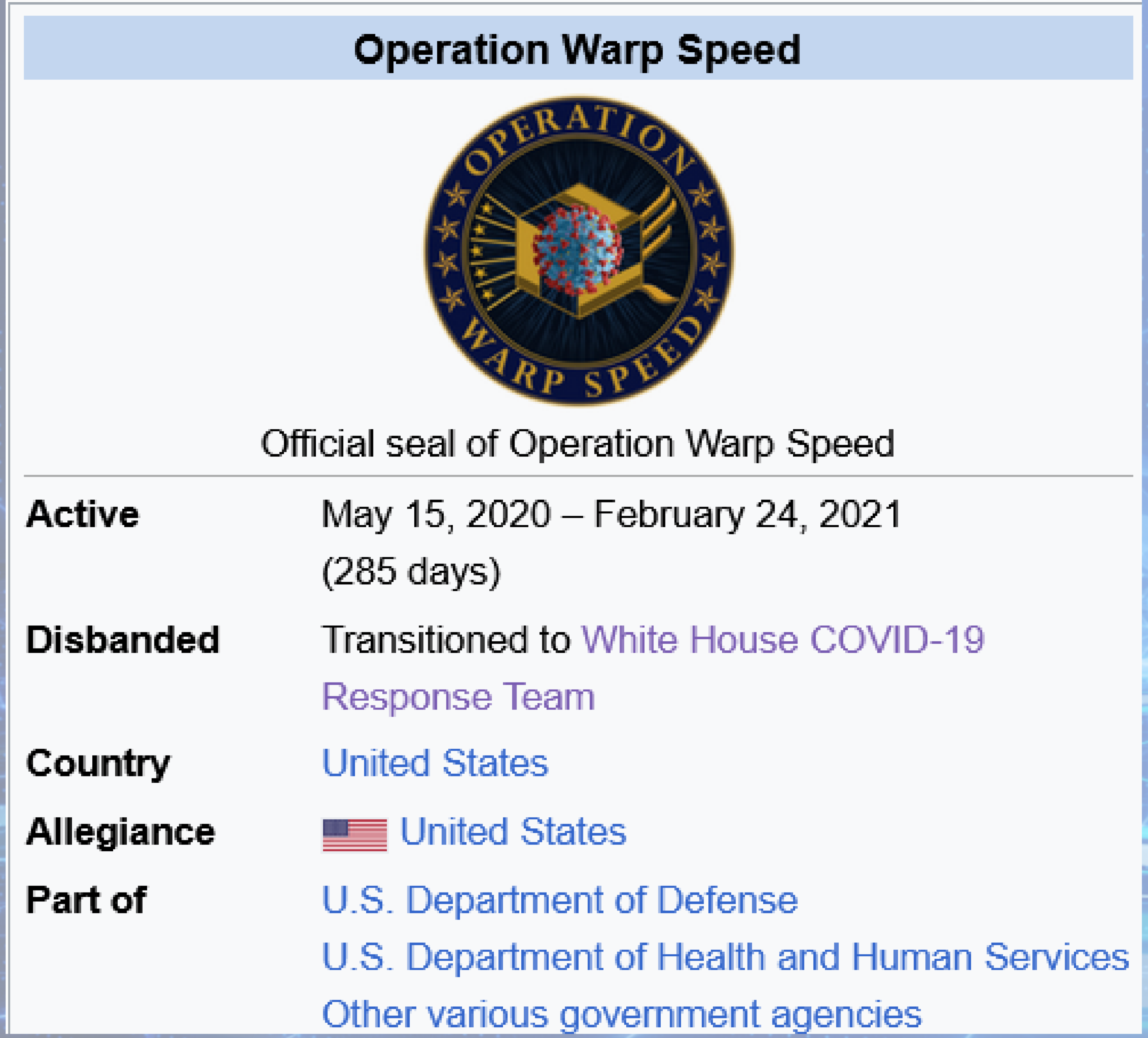
DEPARTMENT

of

DISTRESS

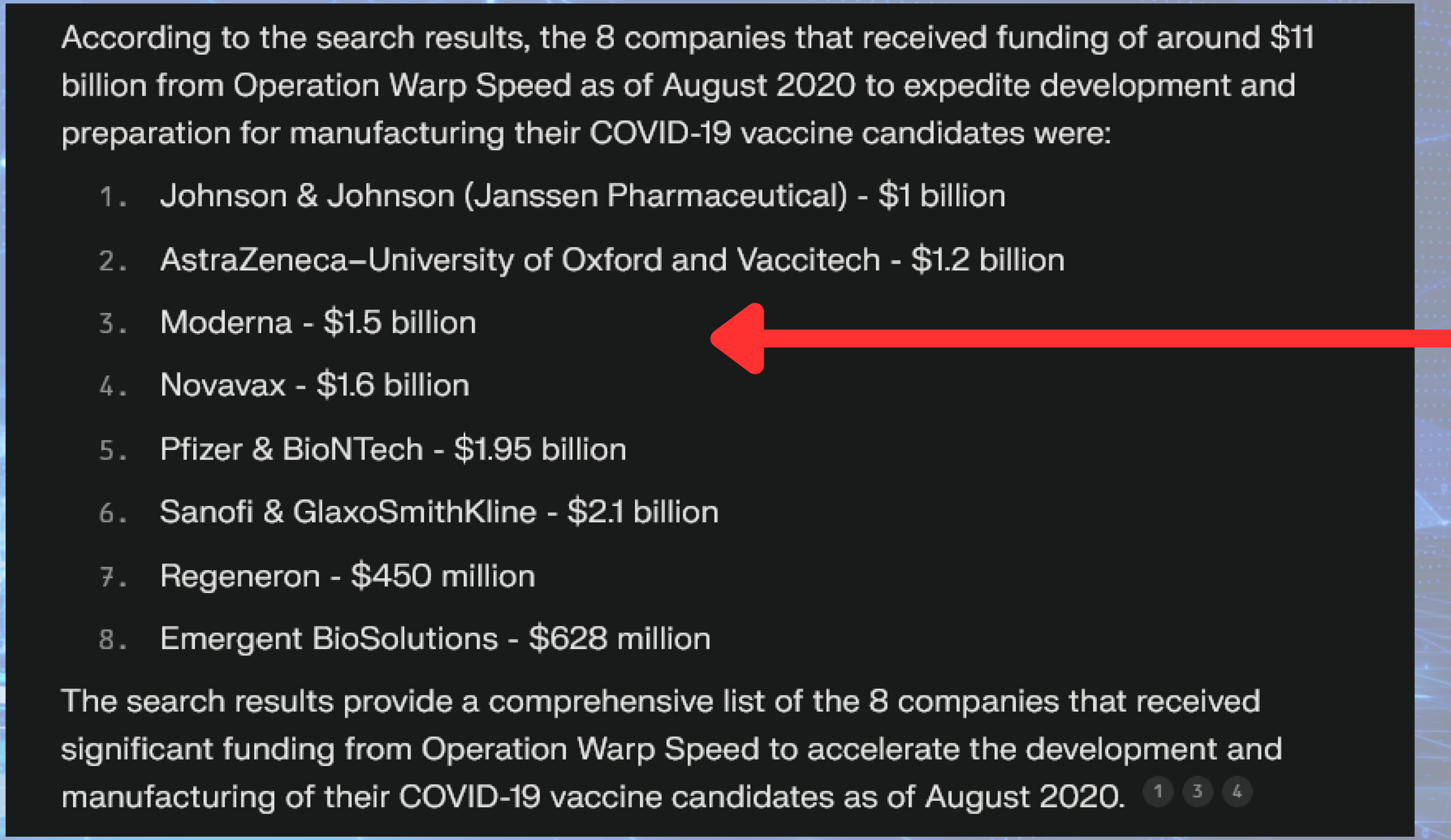
OPERATION WARP SPEED [OWS]



Operation Warp Speed

Official seal of Operation Warp Speed

Active	May 15, 2020 – February 24, 2021 (285 days)
Disbanded	Transitioned to White House COVID-19 Response Team
Country	United States
Allegiance	United States
Part of	U.S. Department of Defense U.S. Department of Health and Human Services Other various government agencies



According to the search results, the 8 companies that received funding of around $11 billion from Operation Warp Speed as of August 2020 to expedite development and preparation for manufacturing their COVID-19 vaccine candidates were:

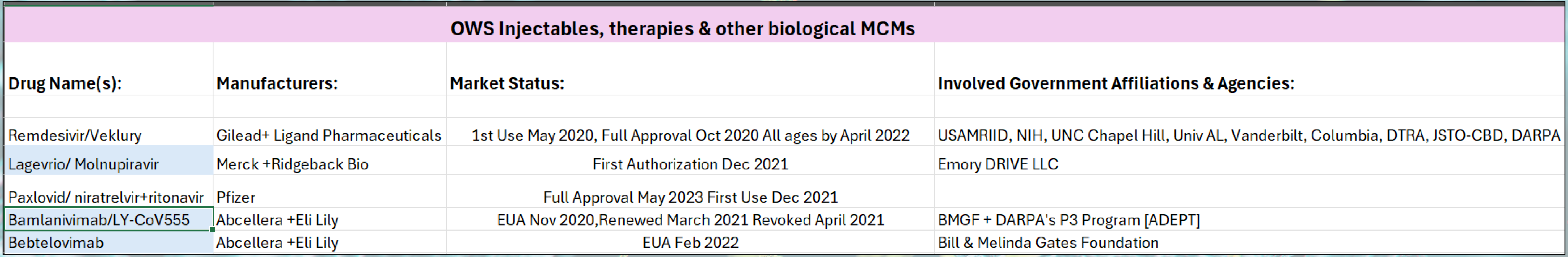
1. Johnson & Johnson (Janssen Pharmaceutical) - $1 billion
2. AstraZeneca–University of Oxford and Vaccitech - $1.2 billion
3. Moderna - $1.5 billion
4. Novavax - $1.6 billion
5. Pfizer & BioNTech - $1.95 billion
6. Sanofi & GlaxoSmithKline - $2.1 billion
7. Regeneron - $450 million
8. Emergent BioSolutions - $628 million

The search results provide a comprehensive list of the 8 companies that received significant funding from Operation Warp Speed to accelerate the development and manufacturing of their COVID-19 vaccine candidates as of August 2020. ① ③ ④

DoD + HHS

In total 8 companies were backed by OWS

OWS MCM Enterprise & Responsible Participants



OWS Injectables, therapies & other biological MCMs

Drug Name(s):	**Manufacturers:**	**Market Status:**	**Involved Government Affiliations & Agencies:**
Remdesivir/Veklury	Gilead+ Ligand Pharmaceuticals	1st Use May 2020, Full Approval Oct 2020 All ages by April 2022	USAMRIID, NIH, UNC Chapel Hill, Univ AL, Vanderbilt, Columbia, DTRA, JSTO-CBD, DARPA
Lagevrio/ Molnupiravir	Merck +Ridgeback Bio	First Authorization Dec 2021	Emory DRIVE LLC
Paxlovid/ niratrelvir+ritonavir	Pfizer	Full Approval May 2023 First Use Dec 2021	
Bamlanivimab/LY-CoV555	Abcellera +Eli Lily	EUA Nov 2020,Renewed March 2021 Revoked April 2021	BMGF + DARPA's P3 Program [ADEPT]
Bebtelovimab	Abcellera +Eli Lily	EUA Feb 2022	Bill & Melinda Gates Foundation

Educational Institutions

- Vanderbilt
- UNC Chapel Hill
- Univ. Penn
- Univ TX Med Branch
- Dartmouth
- Emory
- Univ. Alabama
- Johns Hopkins
- Georgetown

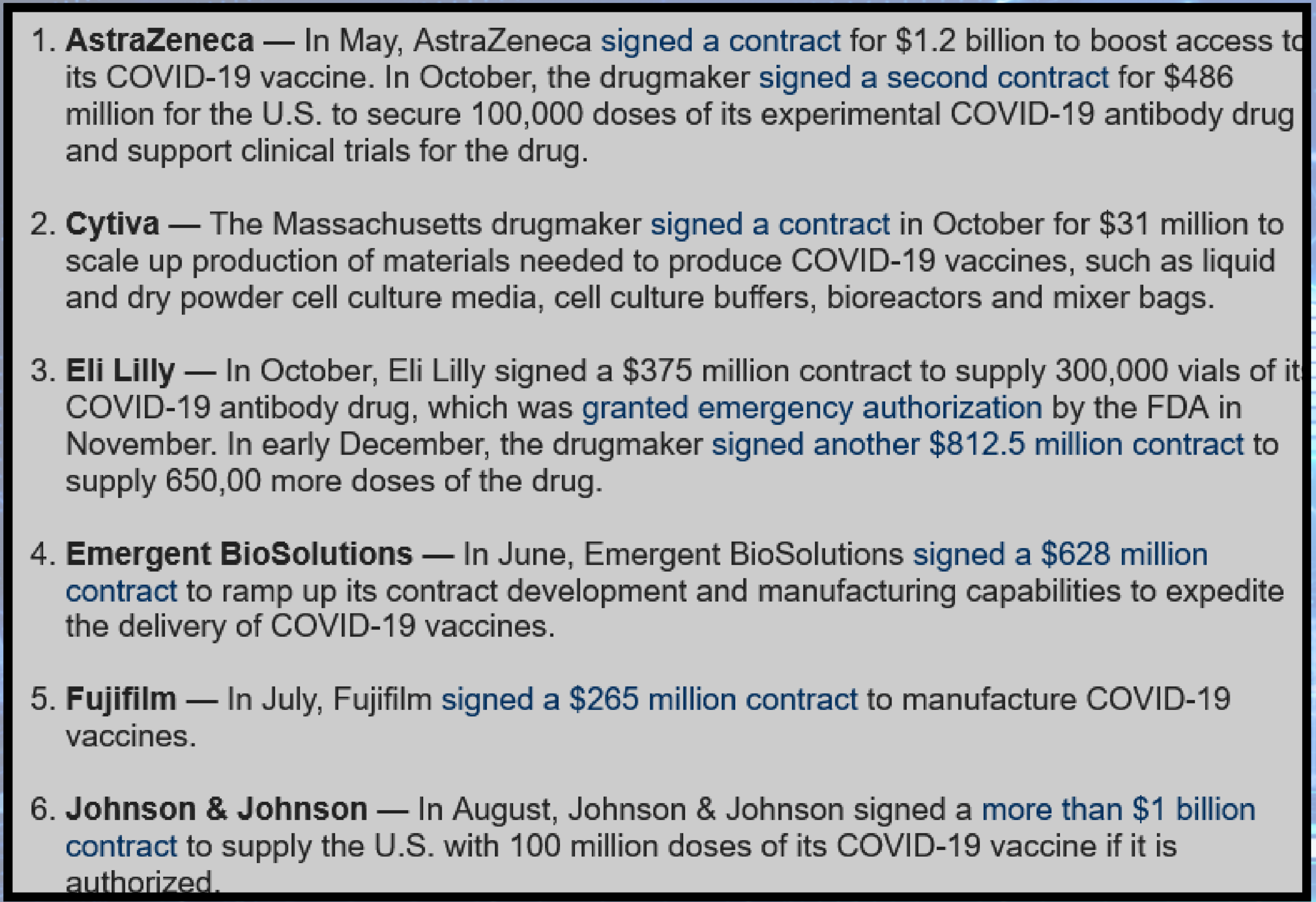
Non-Government Organizations

- Bill & Melinda Gates Foundation [BMGF]
- Scripps
- CEPI
- Wellcome Trust
- EcoHealth Alliance
- In-Q-Tel

Governmental Organizations

- JPEO-CBRN [ARMY]
- NIH/NIAID/FNIH
- DARPA
- DTRA
- BARDA
- ASPR/HHS
- NSF
- DHS-CWMD

OWS Funded MCMs



1. **AstraZeneca** — In May, AstraZeneca signed a contract for $1.2 billion to boost access to its COVID-19 vaccine. In October, the drugmaker signed a second contract for $486 million for the U.S. to secure 100,000 doses of its experimental COVID-19 antibody drug and support clinical trials for the drug.

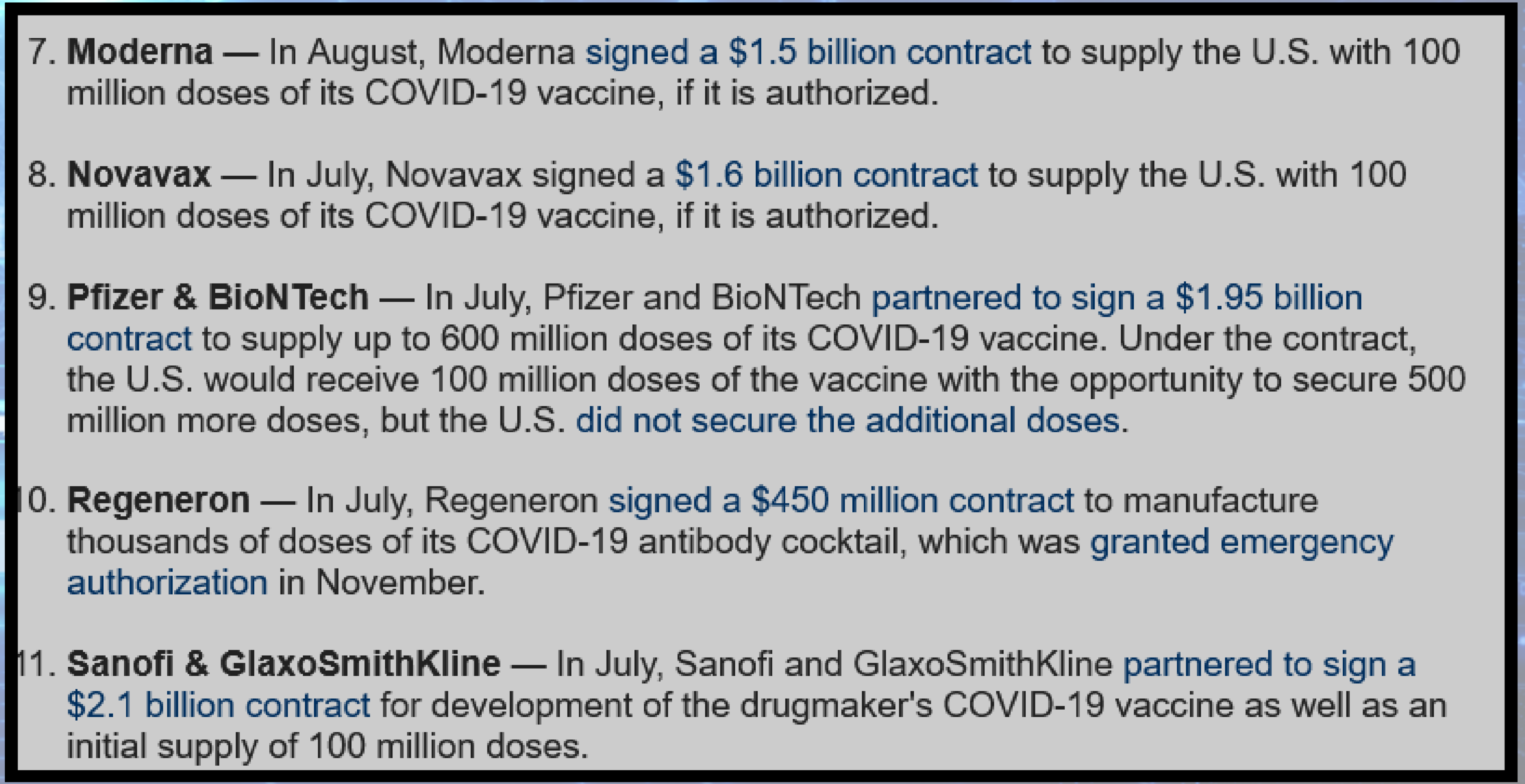
2. **Cytiva** — The Massachusetts drugmaker signed a contract in October for $31 million to scale up production of materials needed to produce COVID-19 vaccines, such as liquid and dry powder cell culture media, cell culture buffers, bioreactors and mixer bags.

3. **Eli Lilly** — In October, Eli Lilly signed a $375 million contract to supply 300,000 vials of it COVID-19 antibody drug, which was granted emergency authorization by the FDA in November. In early December, the drugmaker signed another $812.5 million contract to supply 650,00 more doses of the drug.

4. **Emergent BioSolutions** — In June, Emergent BioSolutions signed a $628 million contract to ramp up its contract development and manufacturing capabilities to expedite the delivery of COVID-19 vaccines.

5. **Fujifilm** — In July, Fujifilm signed a $265 million contract to manufacture COVID-19 vaccines.

6. **Johnson & Johnson** — In August, Johnson & Johnson signed a more than $1 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine if it is authorized.



7. **Moderna** — In August, Moderna signed a $1.5 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

8. **Novavax** — In July, Novavax signed a $1.6 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

9. **Pfizer & BioNTech** — In July, Pfizer and BioNTech partnered to sign a $1.95 billion contract to supply up to 600 million doses of its COVID-19 vaccine. Under the contract, the U.S. would receive 100 million doses of the vaccine with the opportunity to secure 500 million more doses, but the U.S. did not secure the additional doses.

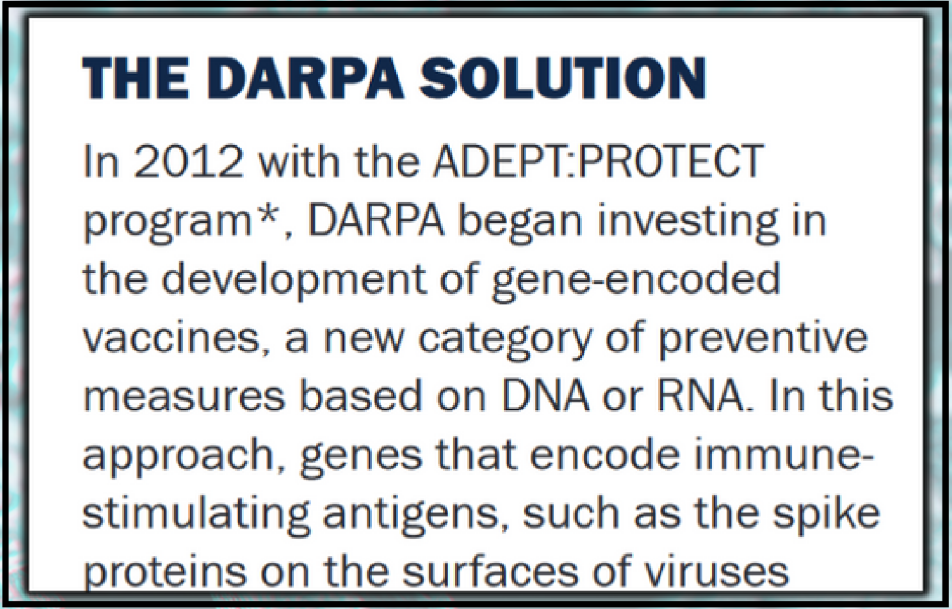
10. **Regeneron** — In July, Regeneron signed a $450 million contract to manufacture thousands of doses of its COVID-19 antibody cocktail, which was granted emergency authorization in November.

11. **Sanofi & GlaxoSmithKline** — In July, Sanofi and GlaxoSmithKline partnered to sign a $2.1 billion contract for development of the drugmaker's COVID-19 vaccine as well as an initial supply of 100 million doses.

HTTPS://WWW.BECKERSHOSPITALREVIEW.COM/PHARMACY/13-DRUGMAKERS-CONTRACTED-BY-OPERATION-WARP-SPEED-IN-2020.HTML

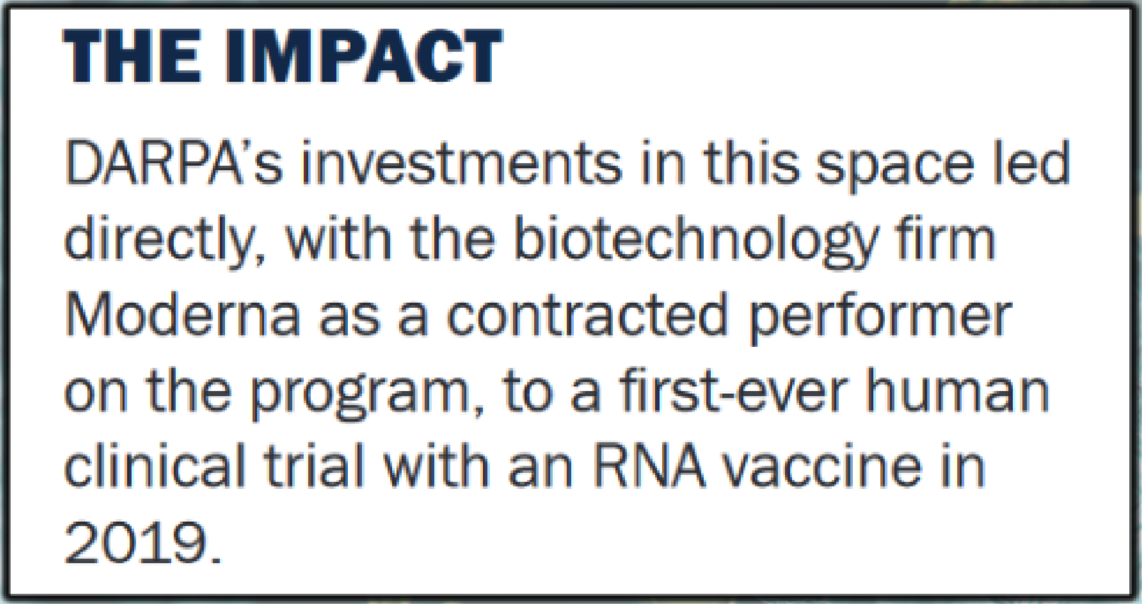
ADEPT : PROTECT

P3



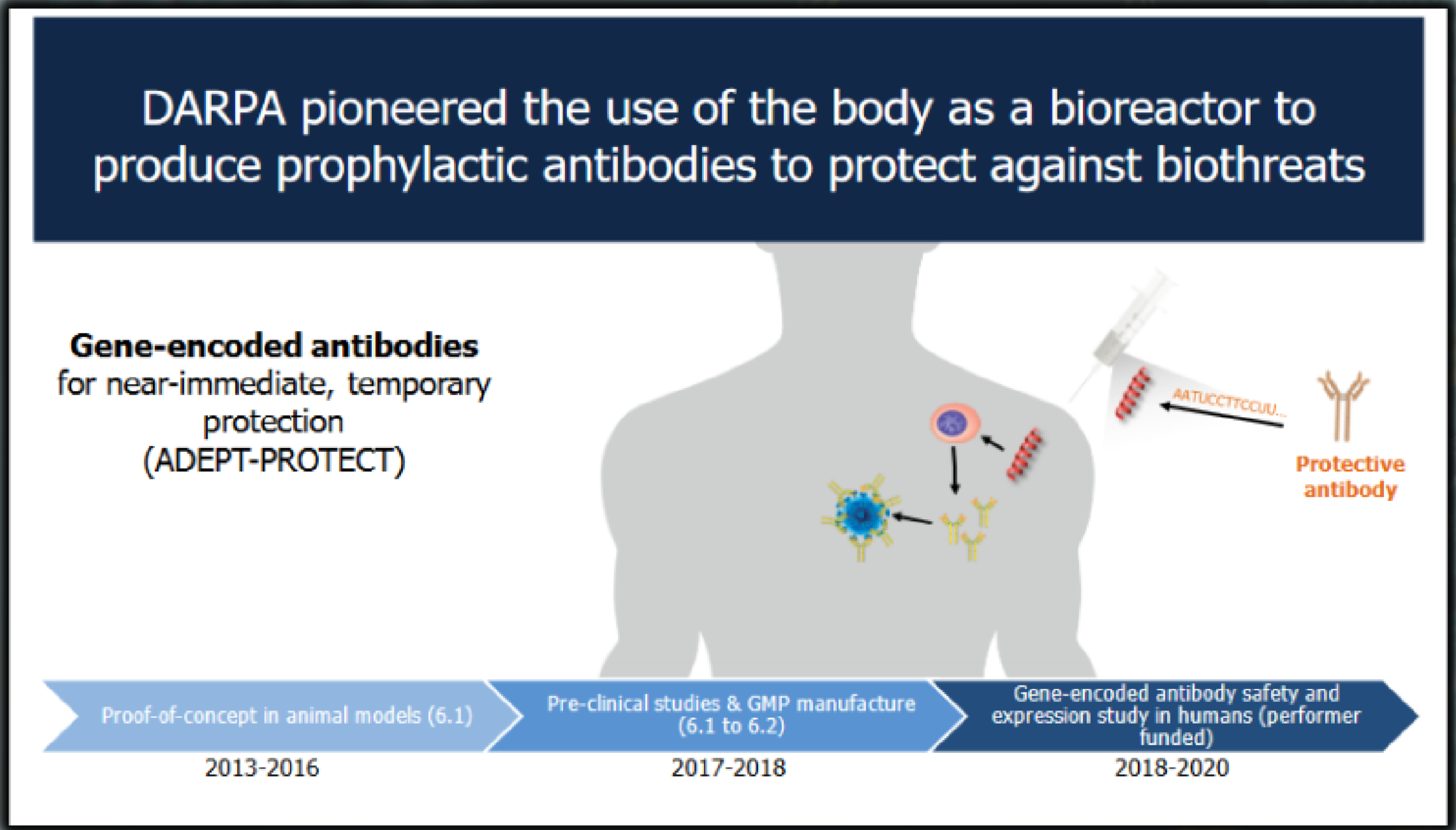
THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses



THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.



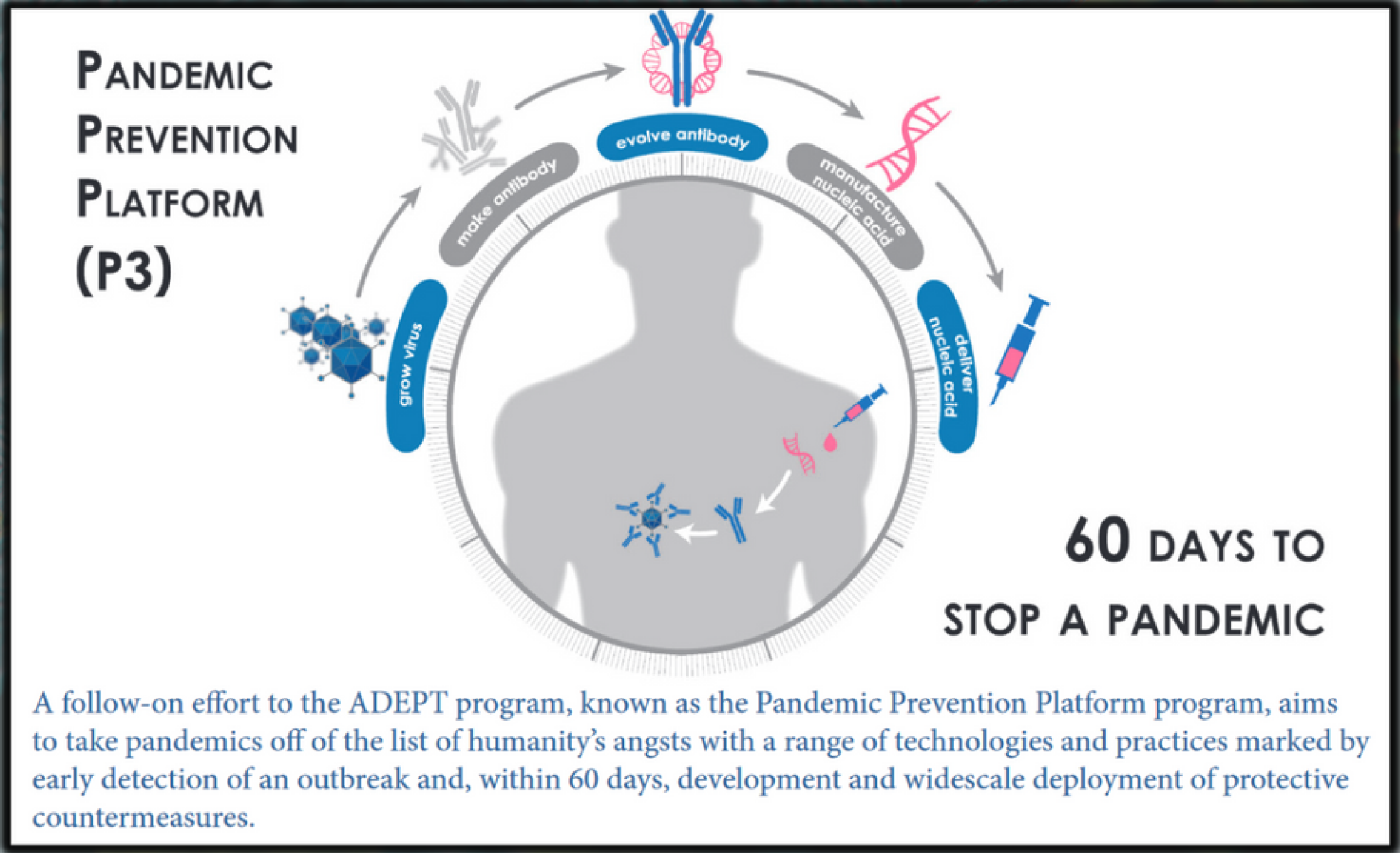
DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

Gene-encoded antibodies
for near-immediate, temporary protection
(ADEPT-PROTECT)

Proof-of-concept in animal models (6.1)
2013-2016

Pre-clinical studies & GMP manufacture (6.1 to 6.2)
2017-2018

Gene-encoded antibody safety and expression study in humans (performer funded)
2018-2020

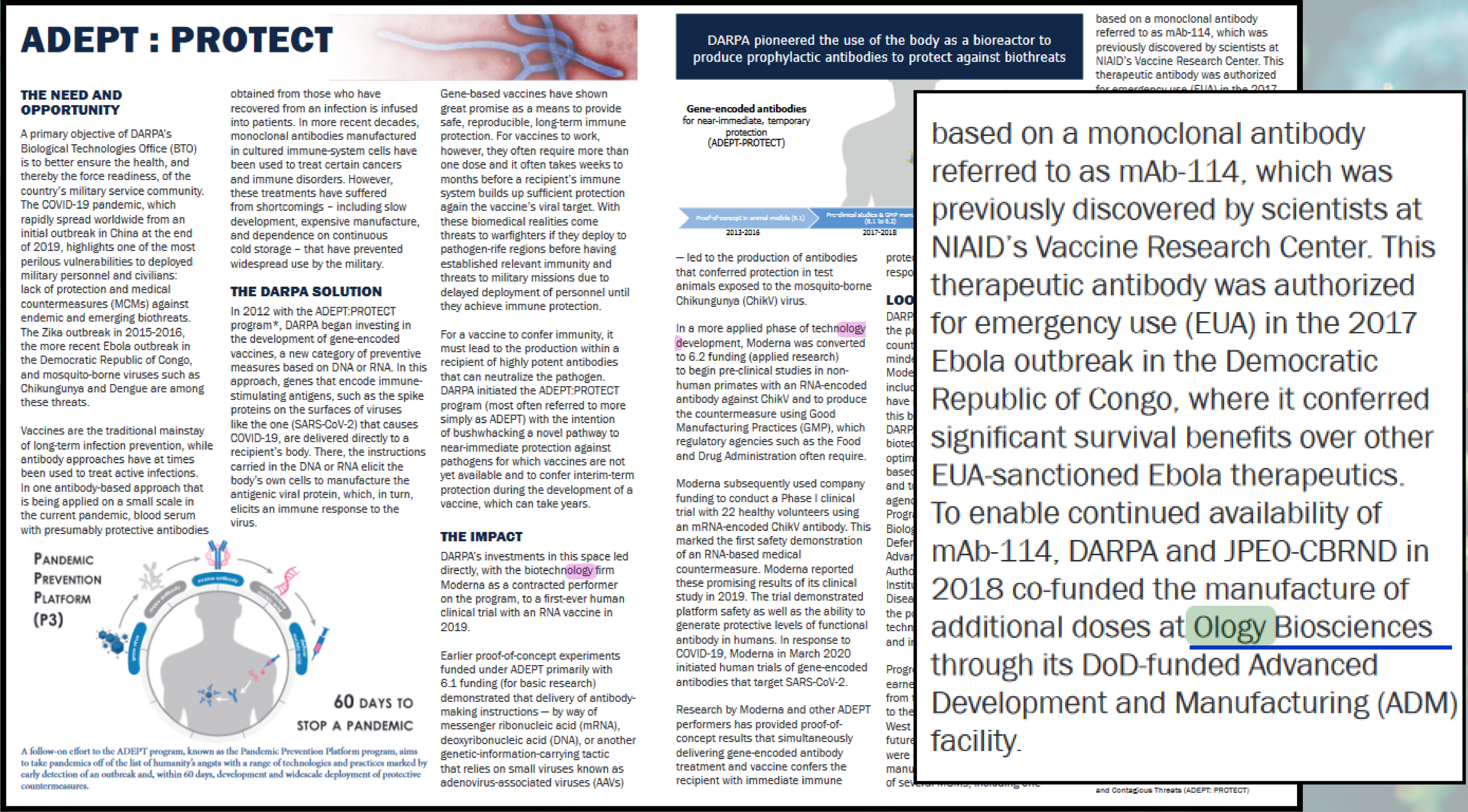


PANDEMIC PREVENTION PLATFORM (P3)

60 DAYS TO
STOP A PANDEMIC

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

https://www.darpa.mil/attachments/ADEPTVignetteFINAL.pdf



ADEPT : PROTECT

THE NEED AND OPPORTUNITY

A primary objective of DARPA's Biological Technologies Office (BTO) is to better ensure the health, and thereby the force readiness, of the country's military service community. The COVID-19 pandemic, which rapidly spread worldwide from an initial outbreak in China at the end of 2019, highlights one of the most perilous vulnerabilities to deployed military personnel and civilians: lack of protection and medical countermeasures (MCMs) against endemic and emerging biothreats. The Zika outbreak in 2015-2016, the more recent Ebola outbreak in the Democratic Republic of Congo, and mosquito-borne viruses such as Chikungunya and Dengue are among these threats.

Vaccines are the traditional mainstay of long-term infection prevention, while antibody approaches have at times been used to treat active infections. In one antibody-based approach that is being applied on a small scale in the current pandemic, blood serum with presumably protective antibodies obtained from those who have recovered from an infection is infused into patients. In more recent decades, monoclonal antibodies manufactured in cultured immune-system cells have been used to treat certain cancers and immune disorders. However, these treatments have suffered from shortcomings – including slow development, expensive manufacture, and dependence on continuous cold storage – that have prevented widespread use by the military.

THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses like the one (SARS-CoV-2) that causes COVID-19, are delivered directly to a recipient's body. There, the instructions carried in the DNA or RNA elicit the body's own cells to manufacture the antigenic viral protein, which, in turn, elicits an immune response to the virus.

Gene-based vaccines have shown great promise as a means to provide safe, reproducible, long-term immune protection. For vaccines to work, however, they often require more than one dose and it often takes weeks to months before a recipient's immune system builds up sufficient protection again the vaccine's viral target. With these biomedical realities come threats to warfighters if they deploy to pathogen-rife regions before having established relevant immunity and threats to military missions due to delayed deployment of personnel until they achieve immune protection.

For a vaccine to confer immunity, it must lead to the production within a recipient of highly potent antibodies that can neutralize the pathogen. DARPA initiated the ADEPT:PROTECT program (most often referred to more simply as ADEPT) with the intention of bushwhacking a novel pathway to near-immediate protection against pathogens for which vaccines are not yet available and to confer interim-term protection during the development of a vaccine, which can take years.

PANDEMIC PREVENTION PLATFORM (P3)

60 DAYS TO STOP A PANDEMIC

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

Earlier proof-of-concept experiments funded under ADEPT primarily with 6.1 funding (for basic research) demonstrated that delivery of antibody-making instructions — by way of messenger ribonucleic acid (mRNA), deoxyribonucleic acid (DNA), or another genetic-information-carrying tactic that relies on small viruses known as adenovirus-associated viruses (AAVs) — led to the production of antibodies that conferred protection in test animals exposed to the mosquito-borne Chikungunya (ChikV) virus.

DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

Gene-encoded antibodies
for near-immediate, temporary protection
(ADEPT-PROTECT)

Proof-of-concept in animal models (6.1)
2013-2016
Pre-clinical studies & GMP man
(6.1 to 6.2)
2017-2018

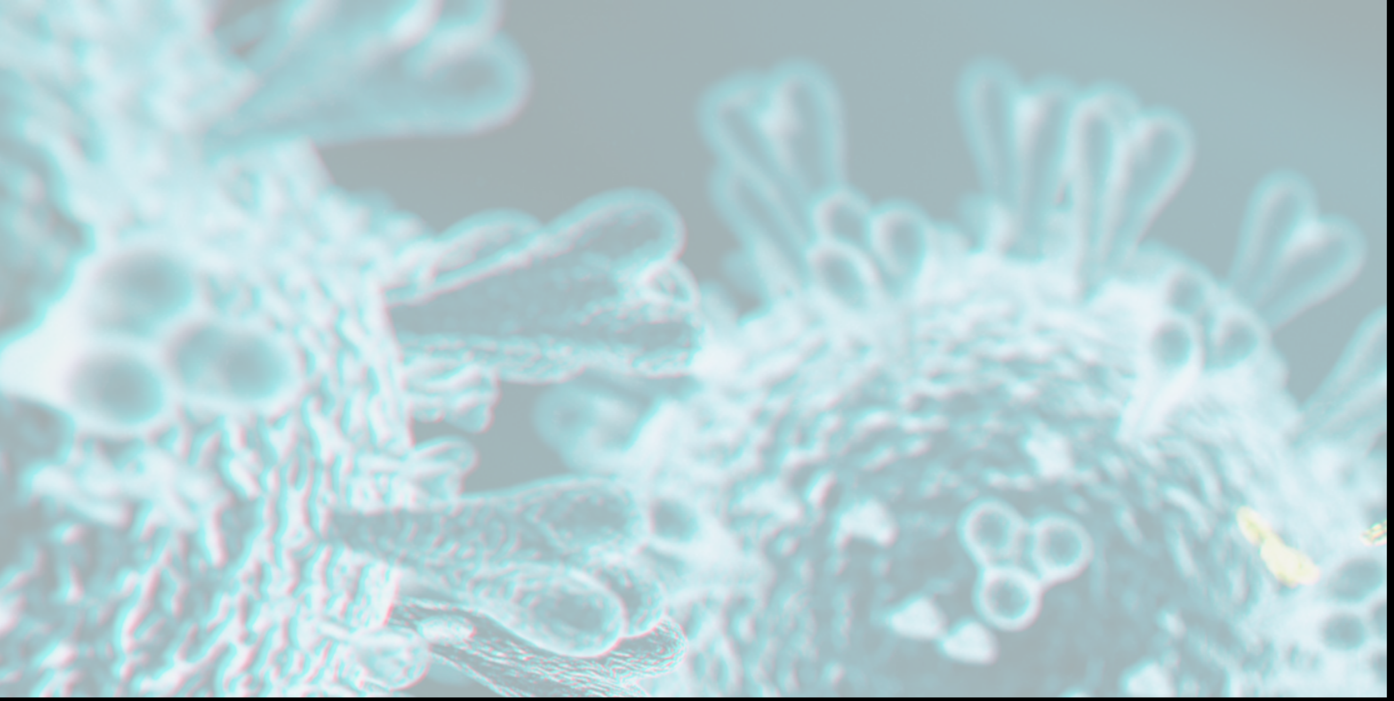
In a more applied phase of technology development, Moderna was converted to 6.2 funding (applied research) to begin pre-clinical studies in non-human primates with an RNA-encoded antibody against ChikV and to produce the countermeasure using Good Manufacturing Practices (GMP), which regulatory agencies such as the Food and Drug Administration often require.

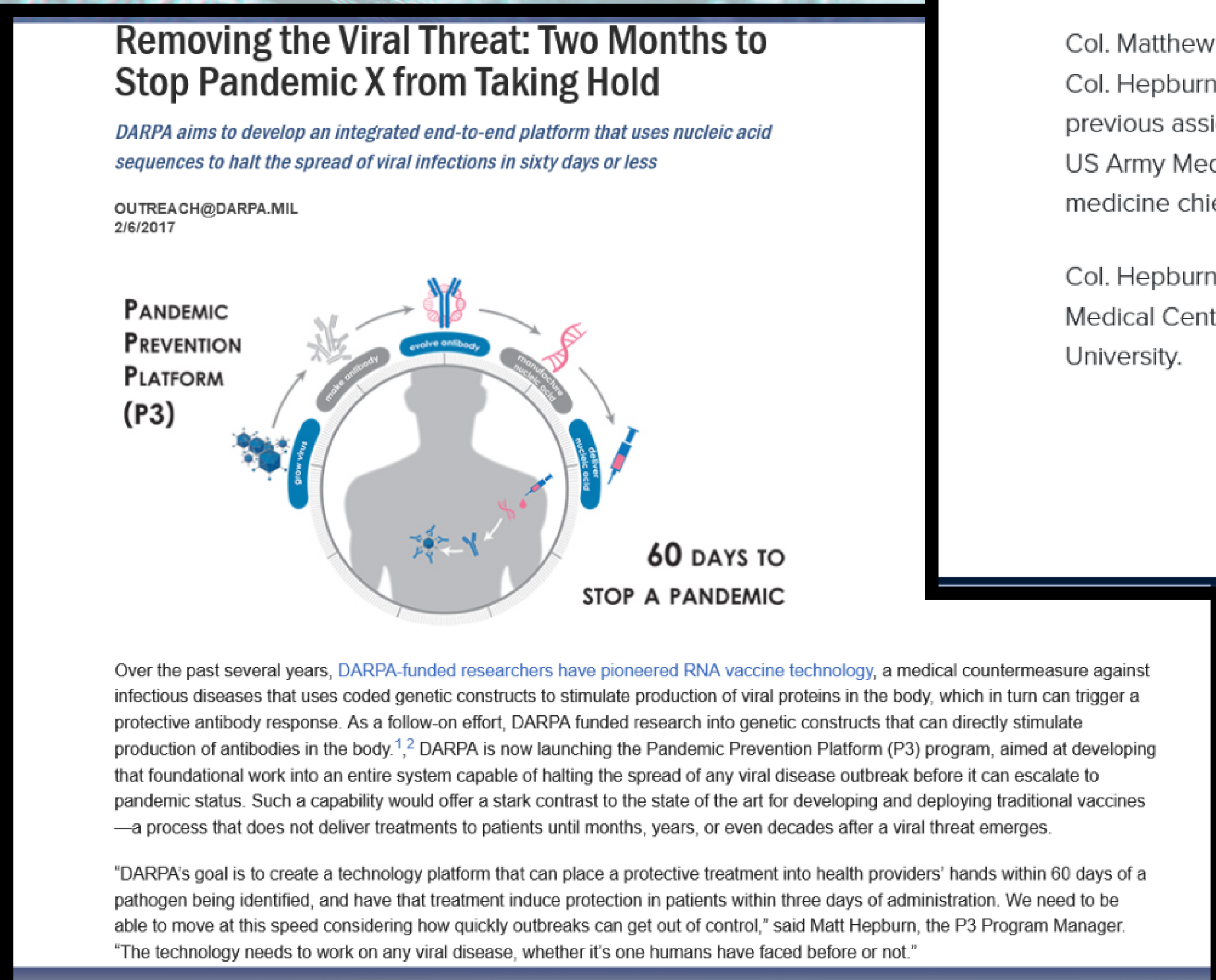
Moderna subsequently used company funding to conduct a Phase I clinical trial with 22 healthy volunteers using an mRNA-encoded ChikV antibody. This marked the first safety demonstration of an RNA-based medical countermeasure. Moderna reported these promising results of its clinical study in 2019. The trial demonstrated platform safety as well as the ability to generate protective levels of functional antibody in humans. In response to COVID-19, Moderna in March 2020 initiated human trials of gene-encoded antibodies that target SARS-CoV-2.

Research by Moderna and other ADEPT performers has provided proof-of-concept results that simultaneously delivering gene-encoded antibody treatment and vaccine confers the recipient with immediate immune

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017 Ebola outbreak in the Democratic Republic of Congo, where it conferred significant survival benefits over other EUA-sanctioned Ebola therapeutics. To enable continued availability of mAb-114, DARPA and JPEO-CBRND in 2018 co-funded the manufacture of additional doses at Ology Biosciences through its DoD-funded Advanced Development and Manufacturing (ADM) facility.

and Contagious Threats (ADEPT: PROTECT)





Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

DARPA aims to develop an integrated end-to-end platform that uses nucleic acid sequences to halt the spread of viral infections in sixty days or less

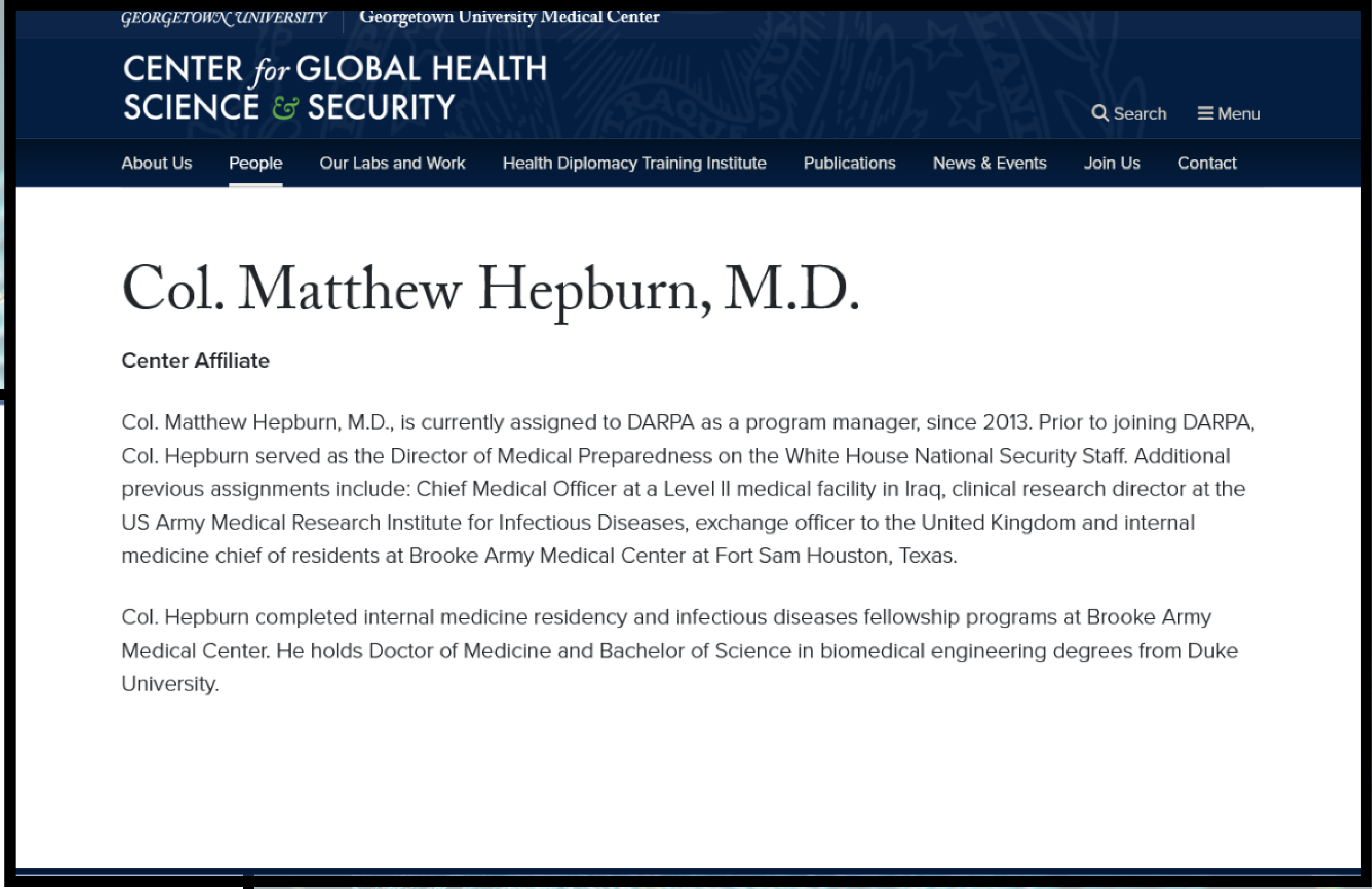
OUTREACH@DARPA.MIL
2/6/2017

PANDEMIC PREVENTION PLATFORM (P3)

60 DAYS TO STOP A PANDEMIC

Over the past several years, DARPA-funded researchers have pioneered RNA vaccine technology, a medical countermeasure against infectious diseases that uses coded genetic constructs to stimulate production of viral proteins in the body, which in turn can trigger a protective antibody response. As a follow-on effort, DARPA funded research into genetic constructs that can directly stimulate production of antibodies in the body.[1],[2] DARPA is now launching the Pandemic Prevention Platform (P3) program, aimed at developing that foundational work into an entire system capable of halting the spread of any viral disease outbreak before it can escalate to pandemic status. Such a capability would offer a stark contrast to the state of the art for developing and deploying traditional vaccines—a process that does not deliver treatments to patients until months, years, or even decades after a viral threat emerges.

"DARPA's goal is to create a technology platform that can place a protective treatment into health providers' hands within 60 days of a pathogen being identified, and have that treatment induce protection in patients within three days of administration. We need to be able to move at this speed considering how quickly outbreaks can get out of control," said Matt Hepburn, the P3 Program Manager. "The technology needs to work on any viral disease, whether it's one humans have faced before or not."



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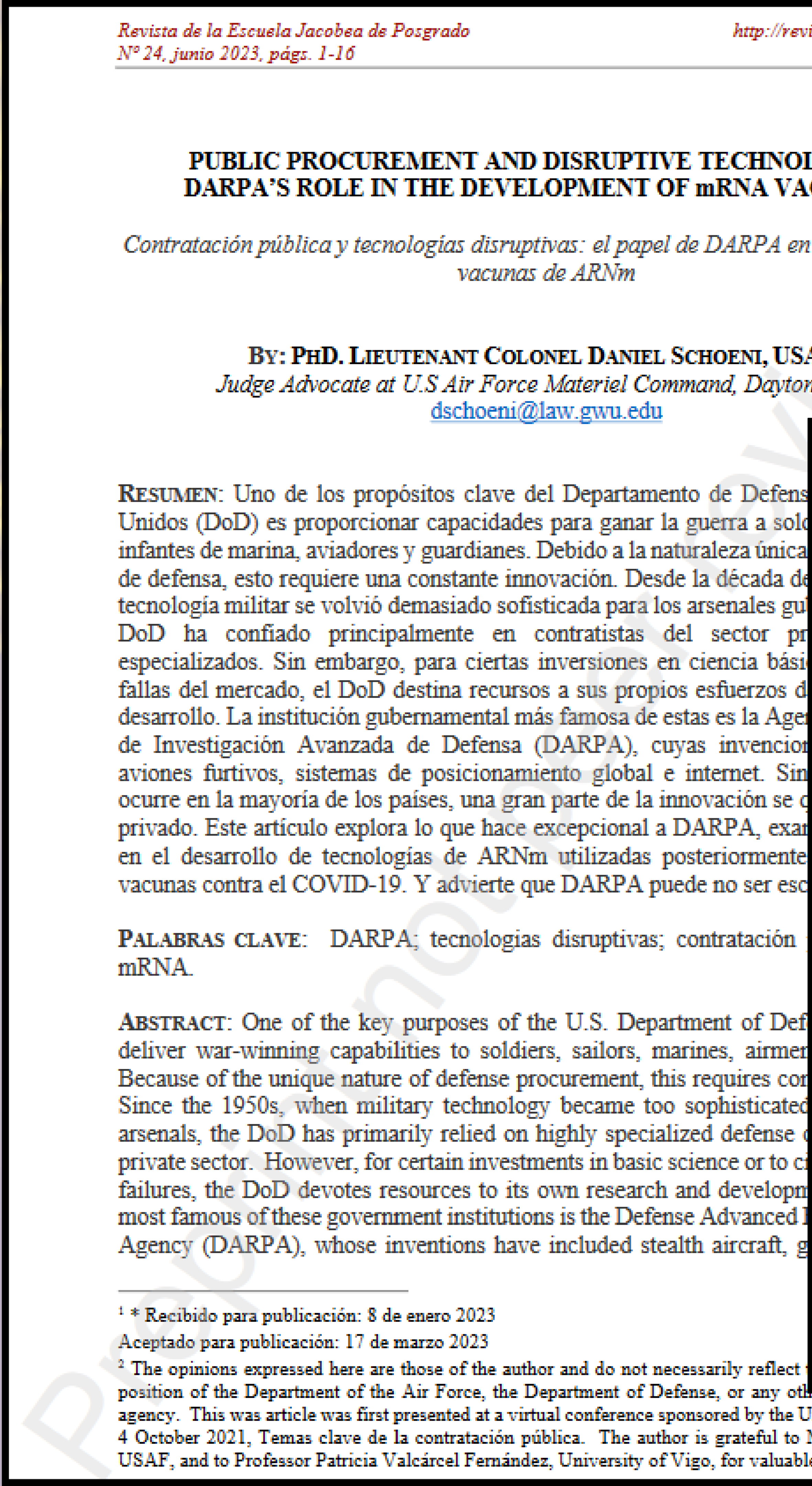
Col. Matthew Hepburn, M.D.

Center Affiliate

Col. Matthew Hepburn, M.D., is currently assigned to DARPA as a program manager, since 2013. Prior to joining DARPA, Col. Hepburn served as the Director of Medical Preparedness on the White House National Security Staff. Additional previous assignments include: Chief Medical Officer at a Level II medical facility in Iraq, clinical research director at the US Army Medical Research Institute for Infectious Diseases, exchange officer to the United Kingdom and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds Doctor of Medicine and Bachelor of Science in biomedical engineering degrees from Duke University.



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PUBLIC PROCUREMENT AND DISRUPTIVE TECHNOLOGIES: DARPA'S ROLE IN THE DEVELOPMENT OF mRNA VACCINES[1]

Contratación pública y tecnologías disruptivas: el papel de DARPA en el desarrollo de vacunas de ARNm

BY: PHD. LIEUTENANT COLONEL DANIEL SCHOENI, USAF[2]
Judge Advocate at U.S Air Force Materiel Command, Dayton, Ohio
dschoeni@law.gwu.edu

Preprint not peer reviewed

RESUMEN: Uno de los propósitos clave del Departamento de Defens
Unidos (DoD) es proporcionar capacidades para ganar la guerra a sold
infantes de marina, aviadores y guardianes. Debido a la naturaleza únic
de defensa, esto requiere una constante innovación. Desde la década de
tecnología militar se volvió demasiado sofisticada para los arsenales gu
DoD ha confiado principalmente en contratistas del sector pr
especializados. Sin embargo, para ciertas inversiones en ciencia básic
fallas del mercado, el DoD destina recursos a sus propios esfuerzos d
desarrollo. La institución gubernamental más famosa de estas es la Agen
de Investigación Avanzada de Defensa (DARPA), cuyas invencion
aviones furtivos, sistemas de posicionamiento global e internet. Sin
ocurre en la mayoría de los países, una gran parte de la innovación se
privado. Este artículo explora lo que hace excepcional a DARPA, exam
en el desarrollo de tecnologías de ARNm utilizadas posteriormente
vacunas contra el COVID-19. Y advierte que DARPA puede no ser esc

PALABRAS CLAVE: DARPA; tecnologías disruptivas; contratación
mRNA.

ABSTRACT: One of the key purposes of the U.S. Department of Def
deliver war-winning capabilities to soldiers, sailors, marines, airmen
Because of the unique nature of defense procurement, this requires co
Since the 1950s, when military technology became too sophisticated
arsenals, the DoD has primarily relied on highly specialized defense
private sector. However, for certain investments in basic science or to c
failures, the DoD devotes resources to its own research and developm
most famous of these government institutions is the Defense Advanced
Agency (DARPA), whose inventions have included stealth aircraft, g

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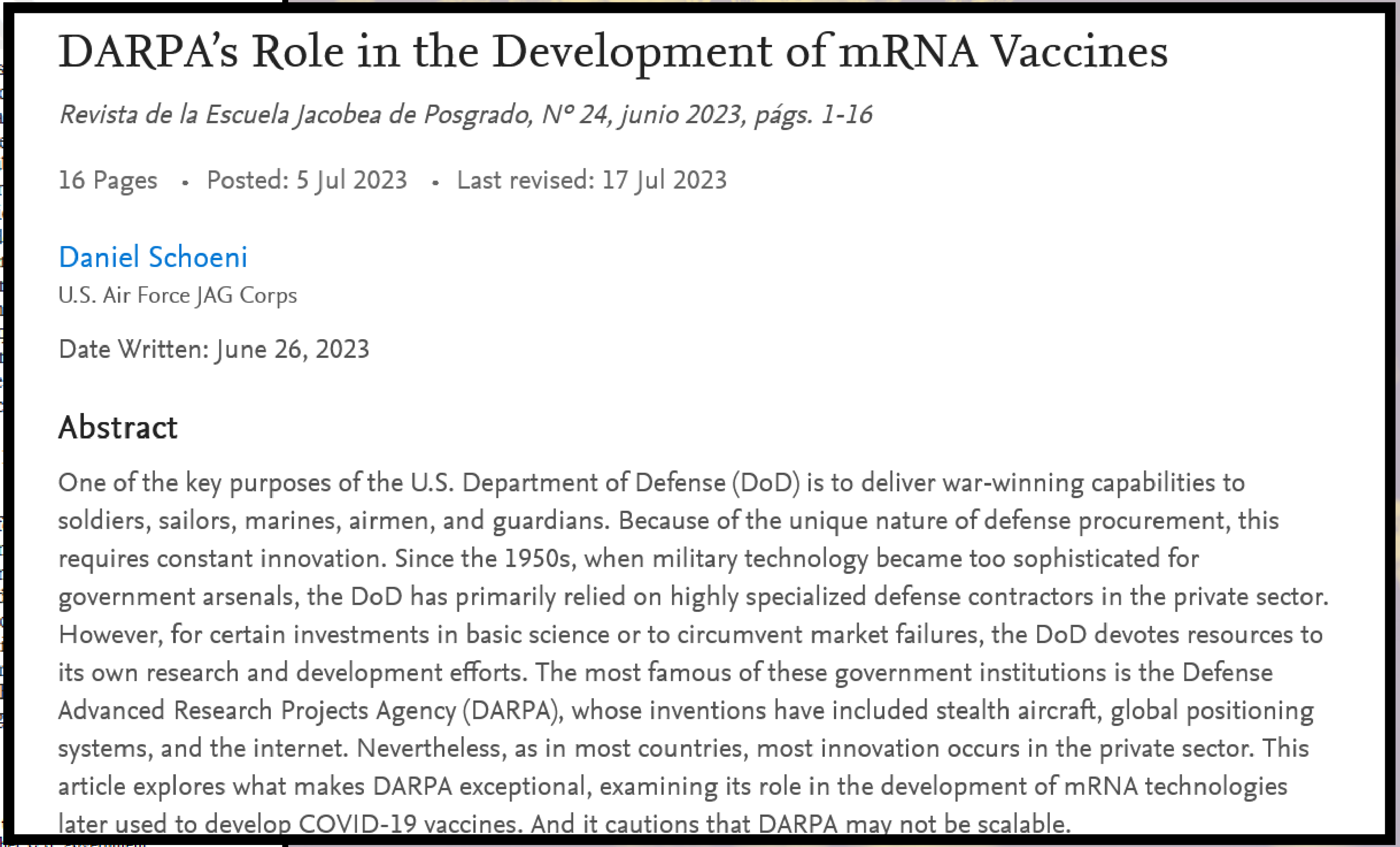
[1] * Recibido para publicación: 8 de enero 2023
Aceptado para publicación: 17 de marzo 2023

[2] The opinions expressed here are those of the author and do not necessarily reflect t
position of the Department of the Air Force, the Department of Defense, or any other U.S. government agency. This was article was first presented at a virtual conference sponsored by the University of Vigo on 4 October 2021, Temas clave de la contratación pública. The author is grateful to Major Ashley Ruhe, USAF, and to Professor Patricia Valcárcel Fernández, University of Vigo, for valuable contributions



DARPA's Role in the Development of mRNA Vaccines

Revista de la Escuela Jacobea de Posgrado, N° 24, junio 2023, págs. 1-16

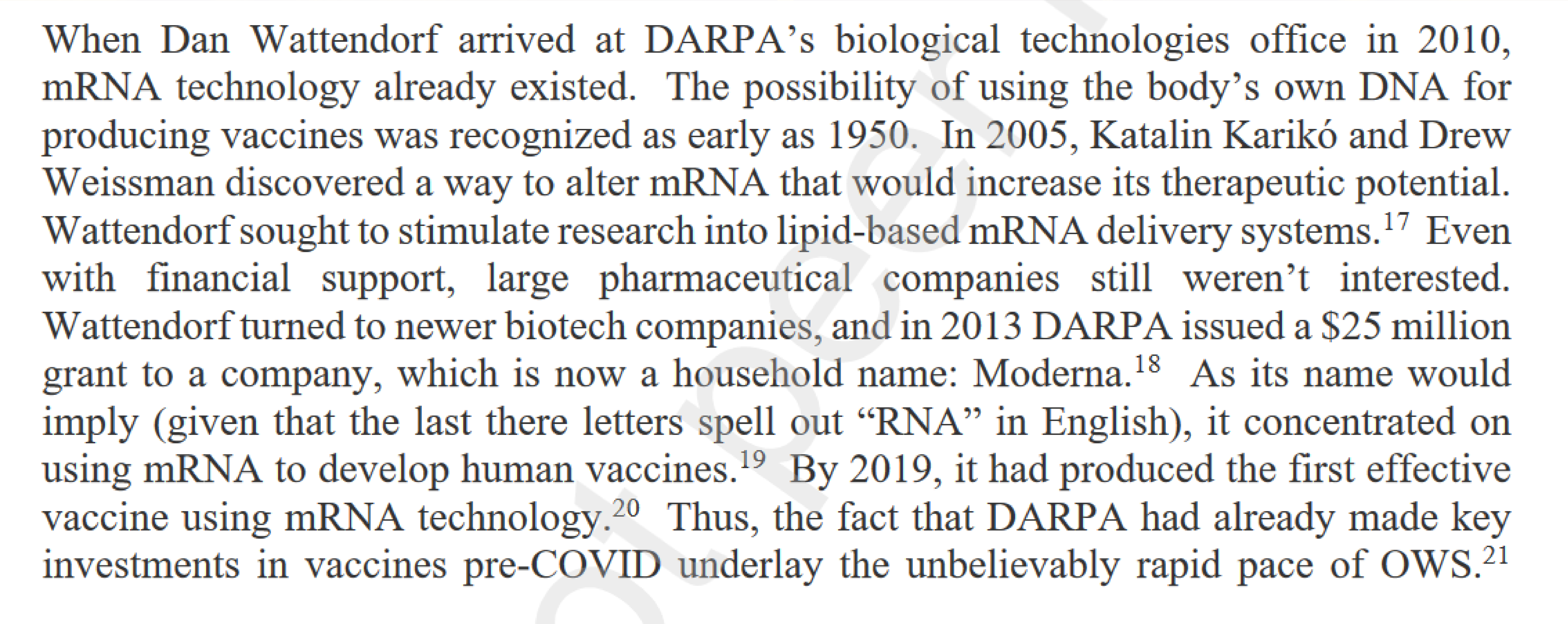
16 Pages • Posted: 5 Jul 2023 • Last revised: 17 Jul 2023

Daniel Schoeni
U.S. Air Force JAG Corps

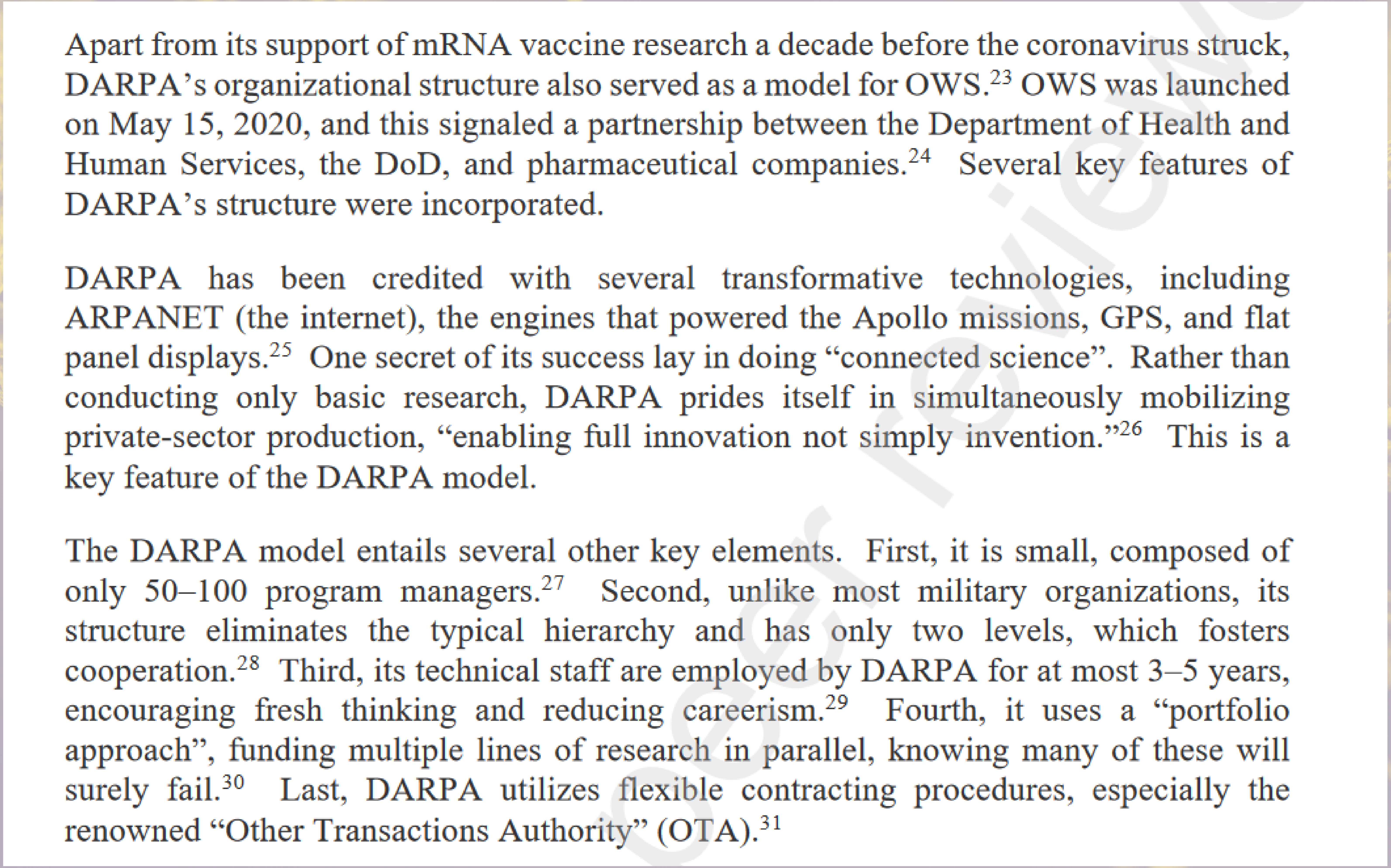
Date Written: June 26, 2023

Abstract

One of the key purposes of the U.S. Department of Defense (DoD) is to deliver war-winning capabilities to soldiers, sailors, marines, airmen, and guardians. Because of the unique nature of defense procurement, this requires constant innovation. Since the 1950s, when military technology became too sophisticated for government arsenals, the DoD has primarily relied on highly specialized defense contractors in the private sector. However, for certain investments in basic science or to circumvent market failures, the DoD devotes resources to its own research and development efforts. The most famous of these government institutions is the Defense Advanced Research Projects Agency (DARPA), whose inventions have included stealth aircraft, global positioning systems, and the internet. Nevertheless, as in most countries, most innovation occurs in the private sector. This article explores what makes DARPA exceptional, examining its role in the development of mRNA technologies later used to develop COVID-19 vaccines. And it cautions that DARPA may not be scalable.



When Dan Wattendorf arrived at DARPA’s biological technologies office in 2010, mRNA technology already existed. The possibility of using the body’s own DNA for producing vaccines was recognized as early as 1950. In 2005, Katalin Karikó and Drew Weissman discovered a way to alter mRNA that would increase its therapeutic potential. Wattendorf sought to stimulate research into lipid-based mRNA delivery systems.[17] Even with financial support, large pharmaceutical companies still weren’t interested. Wattendorf turned to newer biotech companies, and in 2013 DARPA issued a $25 million grant to a company, which is now a household name: Moderna.[18] As its name would imply (given that the last there letters spell out “RNA” in English), it concentrated on using mRNA to develop human vaccines.[19] By 2019, it had produced the first effective vaccine using mRNA technology.[20] Thus, the fact that DARPA had already made key investments in vaccines pre-COVID underlay the unbelievably rapid pace of OWS.[21]



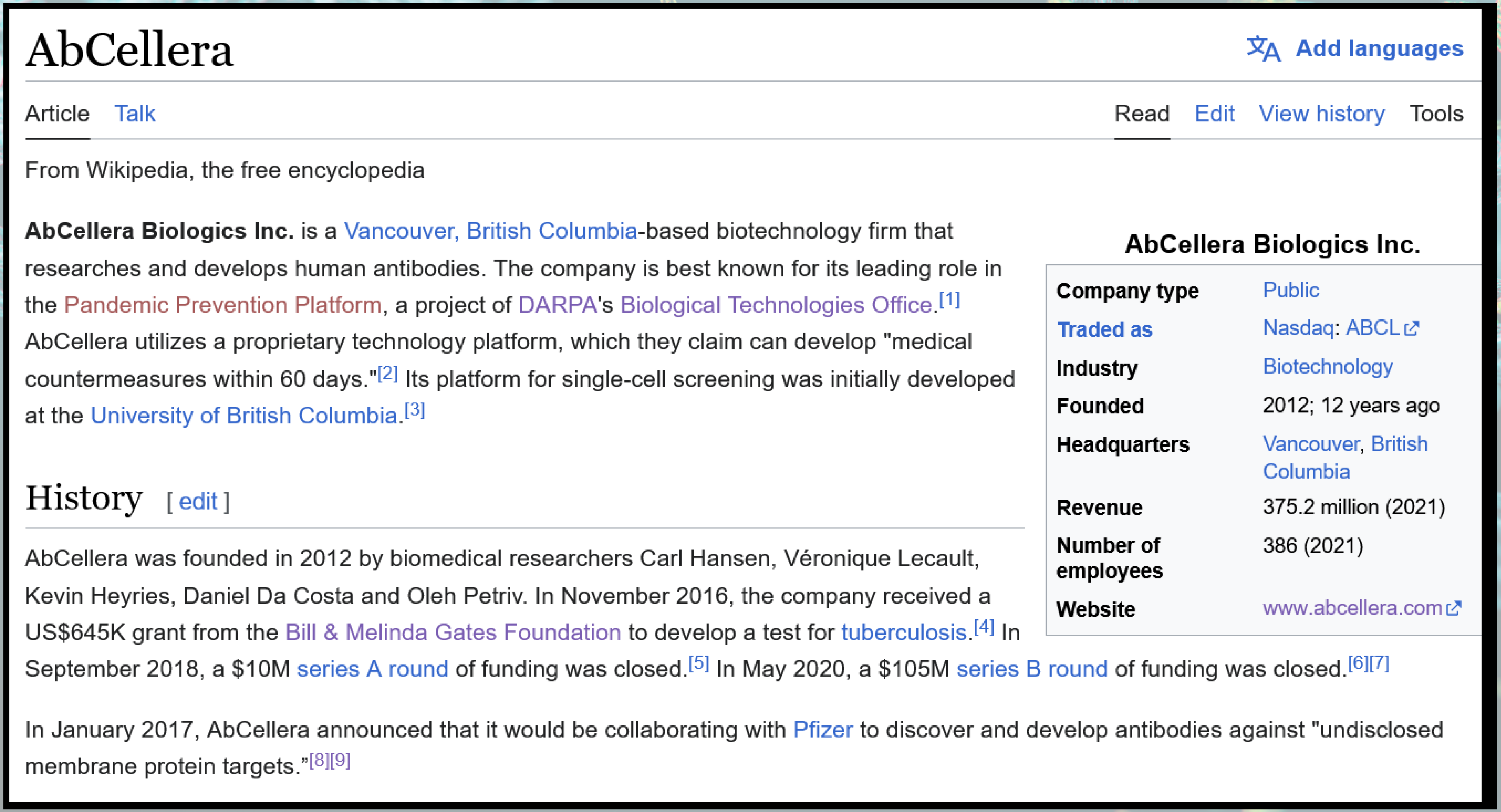
Apart from its support of mRNA vaccine research a decade before the coronavirus struck, DARPA's organizational structure also served as a model for OWS.[23] OWS was launched on May 15, 2020, and this signaled a partnership between the Department of Health and Human Services, the DoD, and pharmaceutical companies.[24] Several key features of DARPA's structure were incorporated.

DARPA has been credited with several transformative technologies, including ARPANET (the internet), the engines that powered the Apollo missions, GPS, and flat panel displays.[25] One secret of its success lay in doing "connected science". Rather than conducting only basic research, DARPA prides itself in simultaneously mobilizing private-sector production, "enabling full innovation not simply invention."[26] This is a key feature of the DARPA model.

The DARPA model entails several other key elements. First, it is small, composed of only 50–100 program managers.[27] Second, unlike most military organizations, its structure eliminates the typical hierarchy and has only two levels, which fosters cooperation.[28] Third, its technical staff are employed by DARPA for at most 3–5 years, encouraging fresh thinking and reducing careerism.[29] Fourth, it uses a "portfolio approach", funding multiple lines of research in parallel, knowing many of these will surely fail.[30] Last, DARPA utilizes flexible contracting procedures, especially the renowned "Other Transactions Authority" (OTA).[31]

peer review

ABCELLERA



AbCellera

From Wikipedia, the free encyclopedia

AbCellera Biologics Inc. is a Vancouver, British Columbia-based biotechnology firm that researches and develops human antibodies. The company is best known for its leading role in the Pandemic Prevention Platform, a project of DARPA's Biological Technologies Office.[1] AbCellera utilizes a proprietary technology platform, which they claim can develop "medical countermeasures within 60 days."[2] Its platform for single-cell screening was initially developed at the University of British Columbia.[3]

AbCellera Biologics Inc.

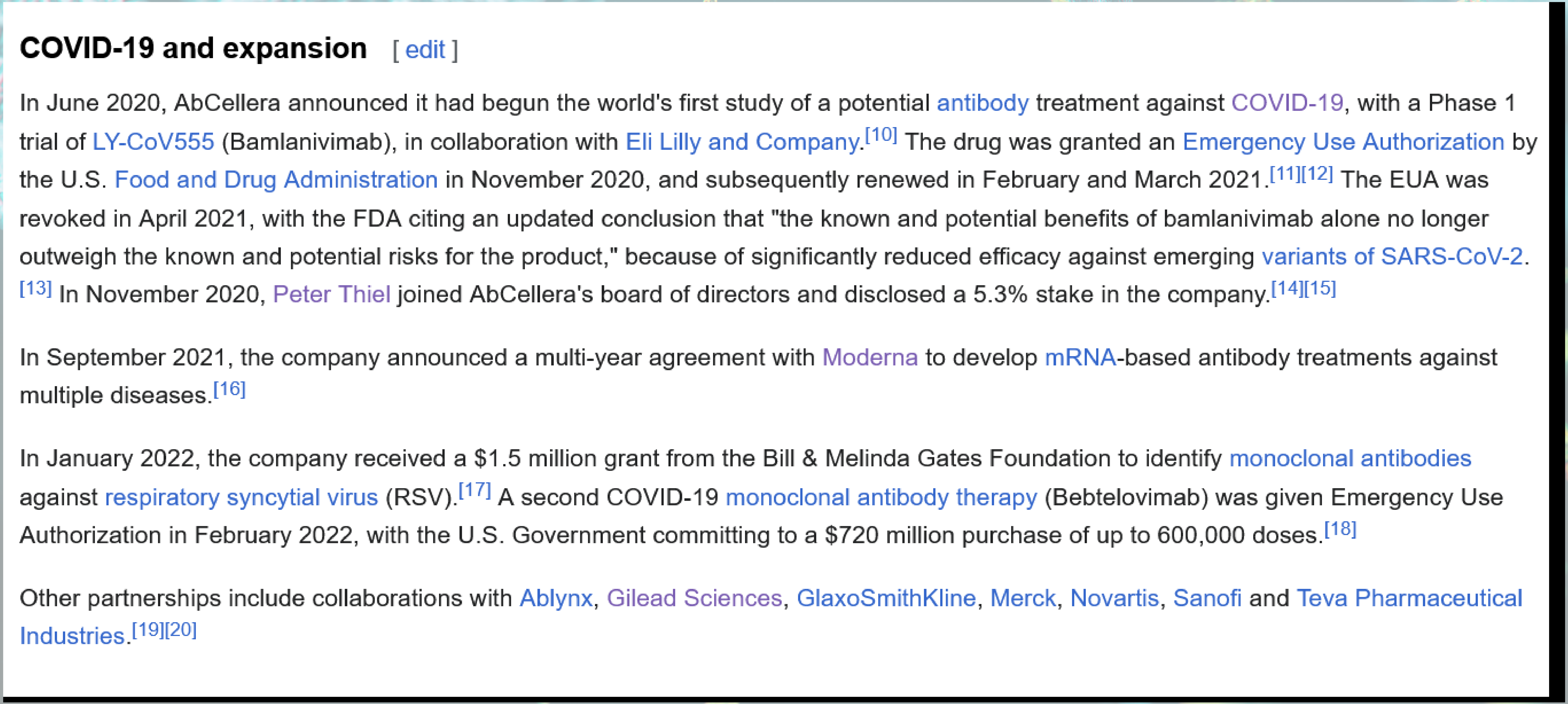
Company type	Public
Traded as	Nasdaq: ABCL
Industry	Biotechnology
Founded	2012; 12 years ago
Headquarters	Vancouver, British Columbia
Revenue	375.2 million (2021)
Number of employees	386 (2021)
Website	www.abcellera.com

History

AbCellera was founded in 2012 by biomedical researchers Carl Hansen, Véronique Lecault, Kevin Heyries, Daniel Da Costa and Oleh Petriv. In November 2016, the company received a US$645K grant from the Bill & Melinda Gates Foundation to develop a test for tuberculosis.[4] In September 2018, a $10M series A round of funding was closed.[5] In May 2020, a $105M series B round of funding was closed.[6][7]

In January 2017, AbCellera announced that it would be collaborating with Pfizer to discover and develop antibodies against "undisclosed membrane protein targets."[8][9]

ABCELLERA



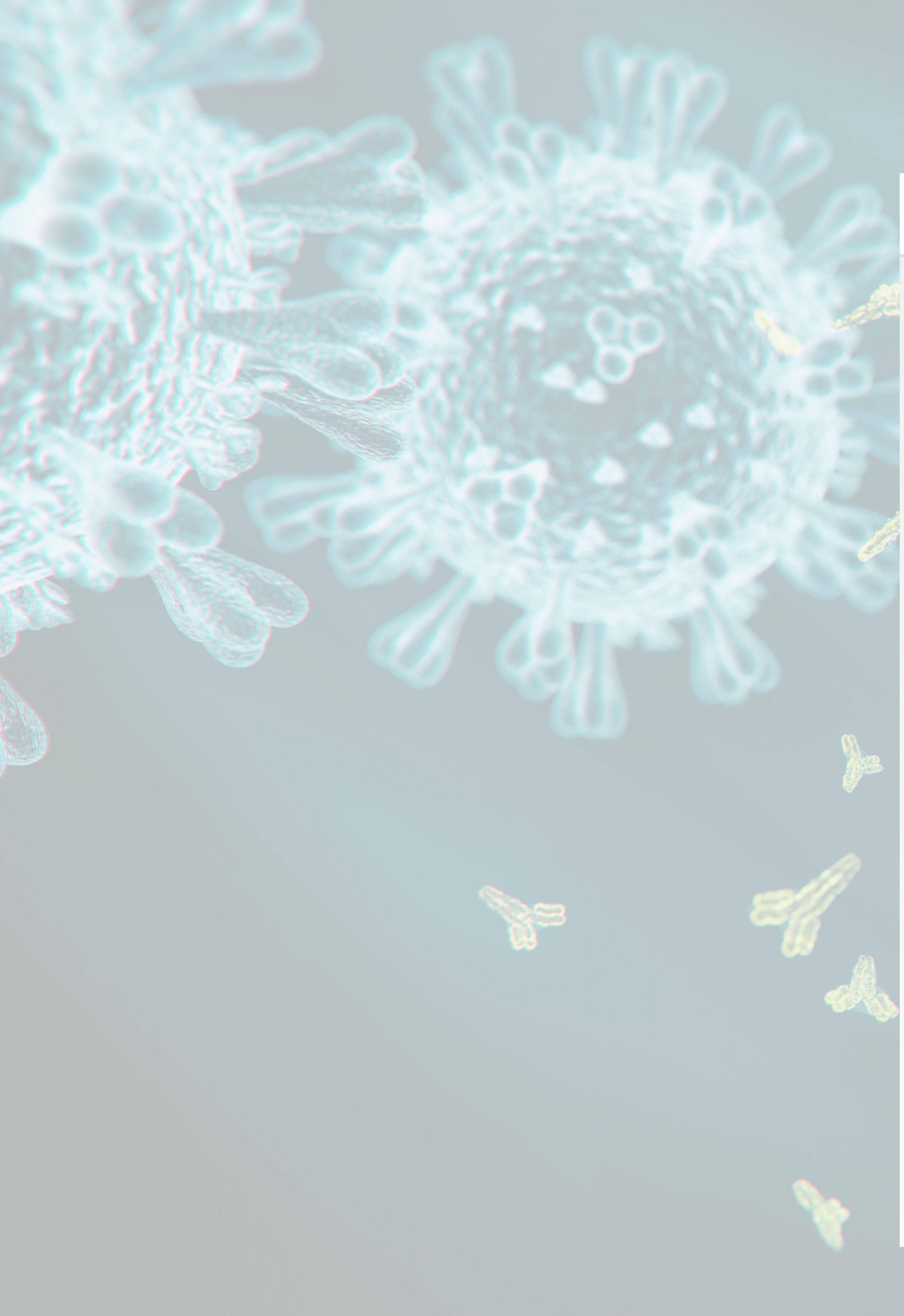
COVID-19 and expansion [edit]

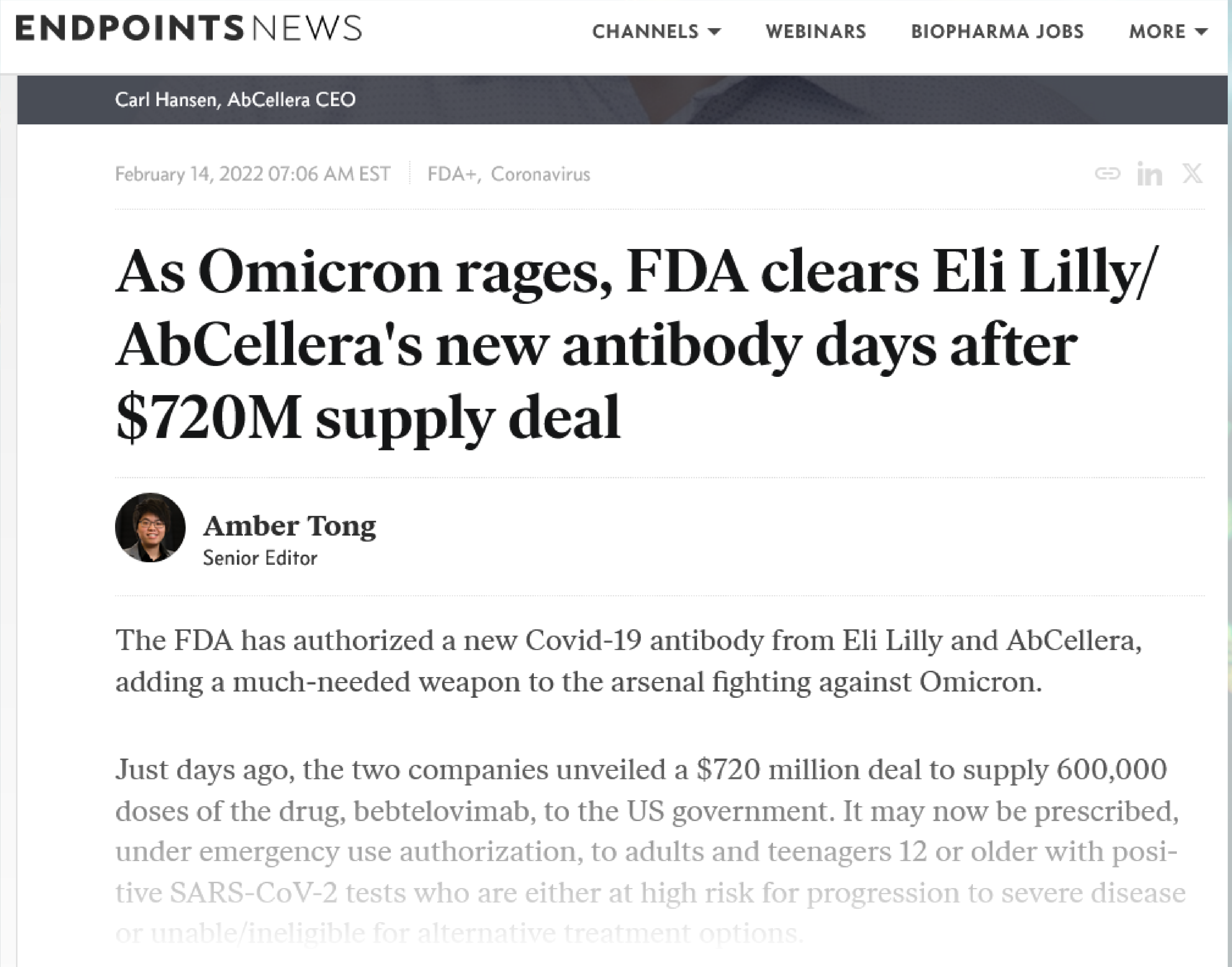
In June 2020, AbCellera announced it had begun the world's first study of a potential antibody treatment against COVID-19, with a Phase 1 trial of LY-CoV555 (Bamlanivimab), in collaboration with Eli Lilly and Company.[10] The drug was granted an Emergency Use Authorization by the U.S. Food and Drug Administration in November 2020, and subsequently renewed in February and March 2021.[11][12] The EUA was revoked in April 2021, with the FDA citing an updated conclusion that "the known and potential benefits of bamlanivimab alone no longer outweigh the known and potential risks for the product," because of significantly reduced efficacy against emerging variants of SARS-CoV-2.[13] In November 2020, Peter Thiel joined AbCellera's board of directors and disclosed a 5.3% stake in the company.[14][15]

In September 2021, the company announced a multi-year agreement with Moderna to develop mRNA-based antibody treatments against multiple diseases.[16]

In January 2022, the company received a $1.5 million grant from the Bill & Melinda Gates Foundation to identify monoclonal antibodies against respiratory syncytial virus (RSV).[17] A second COVID-19 monoclonal antibody therapy (Bebtelovimab) was given Emergency Use Authorization in February 2022, with the U.S. Government committing to a $720 million purchase of up to 600,000 doses.[18]

Other partnerships include collaborations with Ablynx, Gilead Sciences, GlaxoSmithKline, Merck, Novartis, Sanofi and Teva Pharmaceutical Industries.[19][20]





February 14, 2022 07:06 AM EST | FDA+, Coronavirus

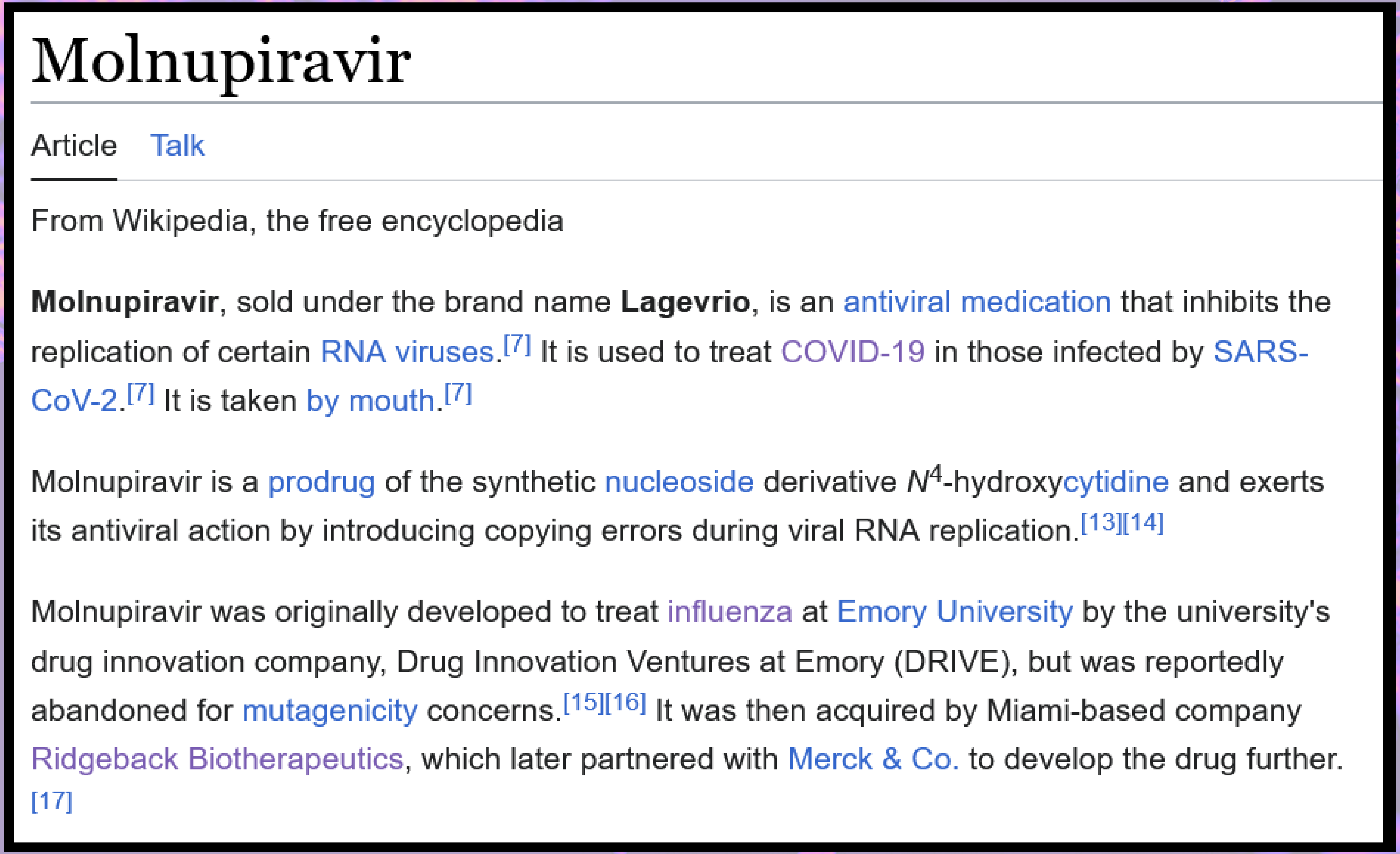
As Omicron rages, FDA clears Eli Lilly/AbCellera's new antibody days after $720M supply deal

Amber Tong
Senior Editor

The FDA has authorized a new Covid-19 antibody from Eli Lilly and AbCellera, adding a much-needed weapon to the arsenal fighting against Omicron.

Just days ago, the two companies unveiled a $720 million deal to supply 600,000 doses of the drug, bebtelovimab, to the US government. It may now be prescribed, under emergency use authorization, to adults and teenagers 12 or older with positive SARS-CoV-2 tests who are either at high risk for progression to severe disease or unable/ineligible for alternative treatment options.

MOLNUPIRAVIR



Molnupiravir

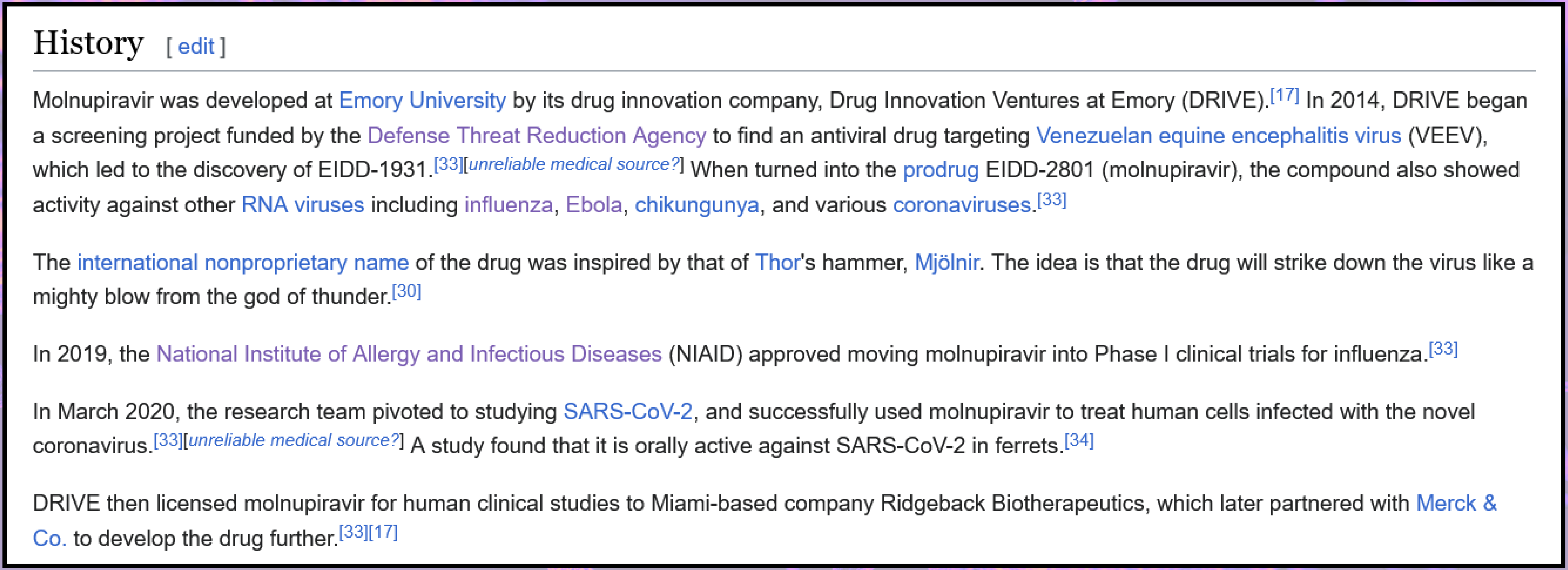
From Wikipedia, the free encyclopedia

Molnupiravir, sold under the brand name **Lagevrio**, is an antiviral medication that inhibits the replication of certain RNA viruses.[7] It is used to treat COVID-19 in those infected by SARS-CoV-2.[7] It is taken by mouth.[7]

Molnupiravir is a prodrug of the synthetic nucleoside derivative N^4-hydroxycytidine and exerts its antiviral action by introducing copying errors during viral RNA replication.[13][14]

Molnupiravir was originally developed to treat influenza at Emory University by the university's drug innovation company, Drug Innovation Ventures at Emory (DRIVE), but was reportedly abandoned for mutagenicity concerns.[15][16] It was then acquired by Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[17]

MOLNUPIRAVIR



History [edit]

Molnupiravir was developed at Emory University by its drug innovation company, Drug Innovation Ventures at Emory (DRIVE).[17] In 2014, DRIVE began a screening project funded by the Defense Threat Reduction Agency to find an antiviral drug targeting Venezuelan equine encephalitis virus (VEEV), which led to the discovery of EIDD-1931.[33][*unreliable medical source?*] When turned into the prodrug EIDD-2801 (molnupiravir), the compound also showed activity against other RNA viruses including influenza, Ebola, chikungunya, and various coronaviruses.[33]

The international nonproprietary name of the drug was inspired by that of Thor's hammer, Mjölnir. The idea is that the drug will strike down the virus like a mighty blow from the god of thunder.[30]

In 2019, the National Institute of Allergy and Infectious Diseases (NIAID) approved moving molnupiravir into Phase I clinical trials for influenza.[33]

In March 2020, the research team pivoted to studying SARS-CoV-2, and successfully used molnupiravir to treat human cells infected with the novel coronavirus.[33][*unreliable medical source?*] A study found that it is orally active against SARS-CoV-2 in ferrets.[34]

DRIVE then licensed molnupiravir for human clinical studies to Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[33][17]

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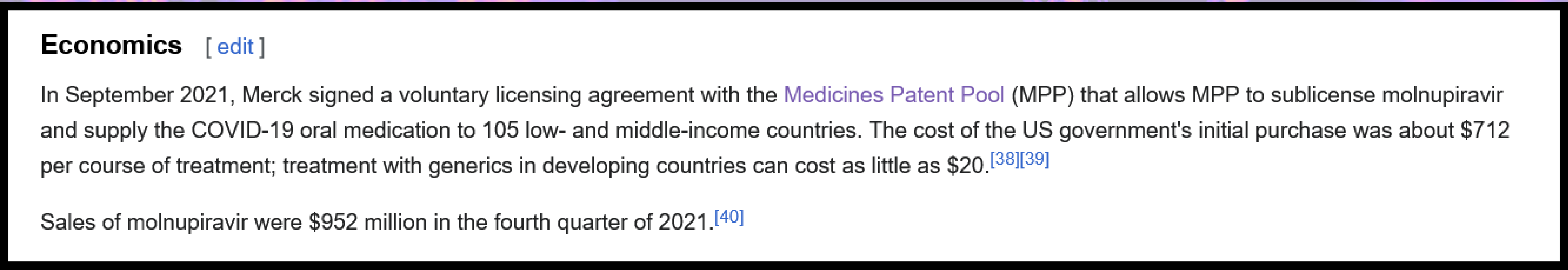
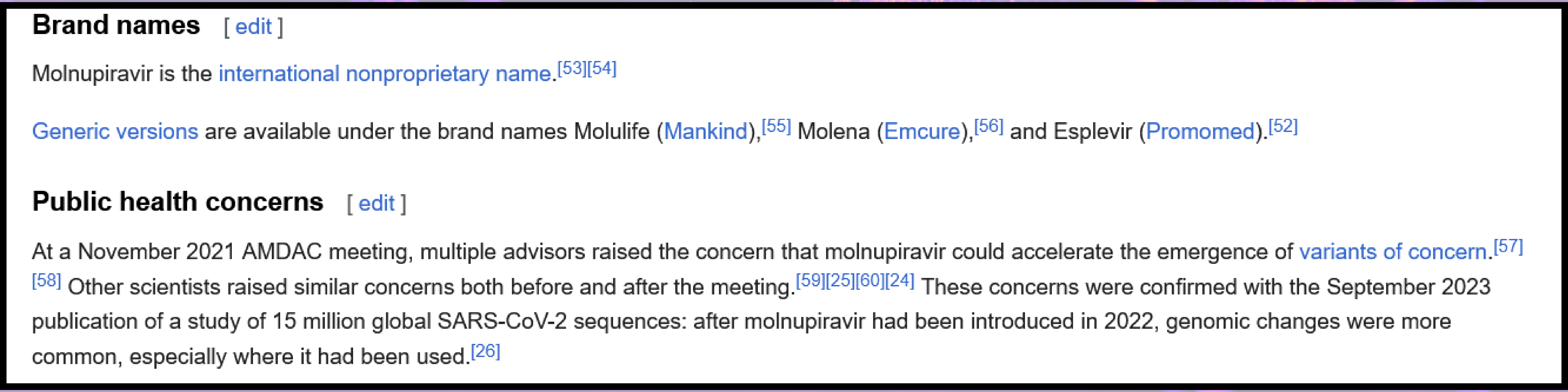


Economics [edit]

In September 2021, Merck signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) that allows MPP to sublicense molnupiravir and supply the COVID-19 oral medication to 105 low- and middle-income countries. The cost of the US government's initial purchase was about $712 per course of treatment; treatment with generics in developing countries can cost as little as $20.[38][39]

Sales of molnupiravir were $952 million in the fourth quarter of 2021.[40]



Brand names [edit]

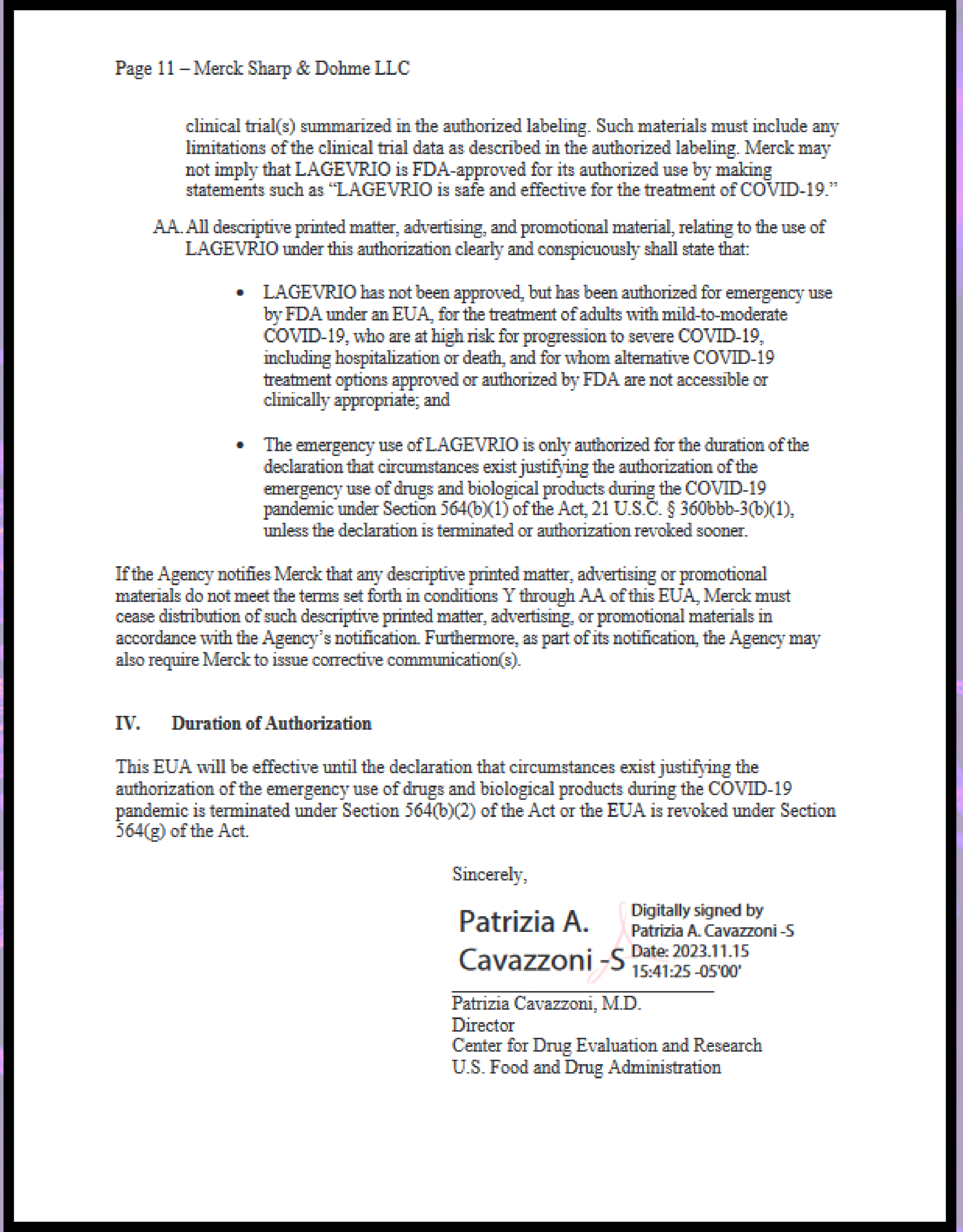
Molnupiravir is the international nonproprietary name.[53][54]

Generic versions are available under the brand names Molulife (Mankind),[55] Molena (Emcure),[56] and Esplevir (Promomed).[52]

Public health concerns [edit]

At a November 2021 AMDAC meeting, multiple advisors raised the concern that molnupiravir could accelerate the emergence of variants of concern.[57][58] Other scientists raised similar concerns both before and after the meeting.[59][25][60][24] These concerns were confirmed with the September 2023 publication of a study of 15 million global SARS-CoV-2 sequences: after molnupiravir had been introduced in 2022, genomic changes were more common, especially where it had been used.[26]

MOLNUPIRAVIR



clinical trial(s) summarized in the authorized labeling. Such materials must include any limitations of the clinical trial data as described in the authorized labeling. Merck may not imply that LAGEVRIO is FDA-approved for its authorized use by making statements such as “LAGEVRIO is safe and effective for the treatment of COVID-19.”

AA. All descriptive printed matter, advertising, and promotional material, relating to the use of LAGEVRIO under this authorization clearly and conspicuously shall state that:

- LAGEVRIO has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults with mild-to-moderate COVID-19, who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate; and

- The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

If the Agency notifies Merck that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions Y through AA of this EUA, Merck must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency’s notification. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A.
Cavazzoni -S
Digitally signed by
Patrizia A. Cavazzoni -S
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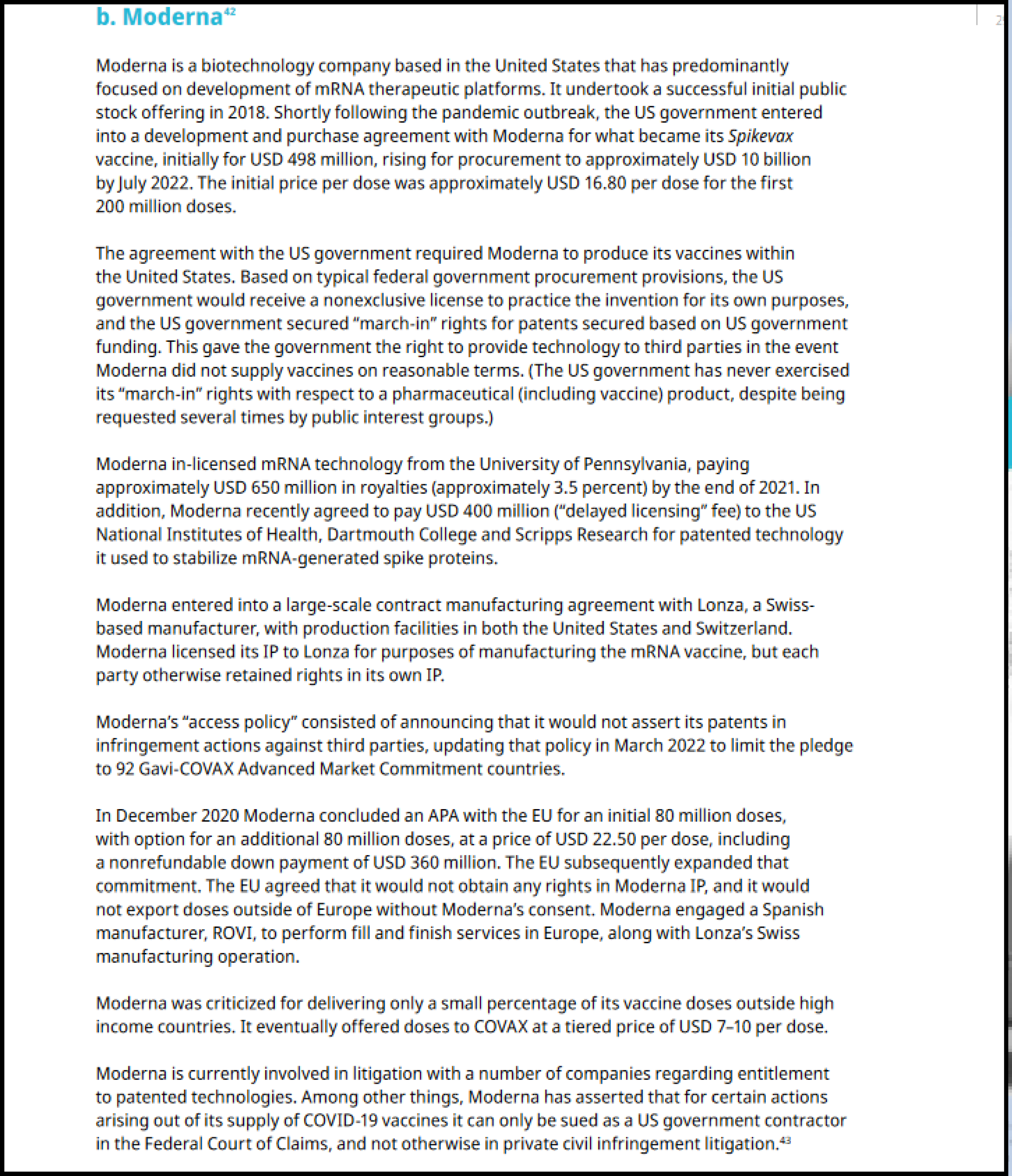
Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



b. Moderna[42]

Moderna is a biotechnology company based in the United States that has predominantly focused on development of mRNA therapeutic platforms. It undertook a successful initial public stock offering in 2018. Shortly following the pandemic outbreak, the US government entered into a development and purchase agreement with Moderna for what became its *Spikevax* vaccine, initially for USD 498 million, rising for procurement to approximately USD 10 billion by July 2022. The initial price per dose was approximately USD 16.80 per dose for the first 200 million doses.

The agreement with the US government required Moderna to produce its vaccines within the United States. Based on typical federal government procurement provisions, the US government would receive a nonexclusive license to practice the invention for its own purposes, and the US government secured "march-in" rights for patents secured based on US government funding. This gave the government the right to provide technology to third parties in the event Moderna did not supply vaccines on reasonable terms. (The US government has never exercised its "march-in" rights with respect to a pharmaceutical (including vaccine) product, despite being requested several times by public interest groups.)

Moderna in-licensed mRNA technology from the University of Pennsylvania, paying approximately USD 650 million in royalties (approximately 3.5 percent) by the end of 2021. In addition, Moderna recently agreed to pay USD 400 million ("delayed licensing" fee) to the US National Institutes of Health, Dartmouth College and Scripps Research for patented technology it used to stabilize mRNA-generated spike proteins.

Moderna entered into a large-scale contract manufacturing agreement with Lonza, a Swiss-based manufacturer, with production facilities in both the United States and Switzerland. Moderna licensed its IP to Lonza for purposes of manufacturing the mRNA vaccine, but each party otherwise retained rights in its own IP.

Moderna's "access policy" consisted of announcing that it would not assert its patents in infringement actions against third parties, updating that policy in March 2022 to limit the pledge to 92 Gavi-COVAX Advanced Market Commitment countries.

In December 2020 Moderna concluded an APA with the EU for an initial 80 million doses, with option for an additional 80 million doses, at a price of USD 22.50 per dose, including a nonrefundable down payment of USD 360 million. The EU subsequently expanded that commitment. The EU agreed that it would not obtain any rights in Moderna IP, and it would not export doses outside of Europe without Moderna's consent. Moderna engaged a Spanish manufacturer, ROVI, to perform fill and finish services in Europe, along with Lonza's Swiss manufacturing operation.

Moderna was criticized for delivering only a small percentage of its vaccine doses outside high income countries. It eventually offered doses to COVAX at a tiered price of USD 7–10 per dose.

Moderna is currently involved in litigation with a number of companies regarding entitlement to patented technologies. Among other things, Moderna has asserted that for certain actions arising out of its supply of COVID-19 vaccines it can only be sued as a US government contractor in the Federal Court of Claims, and not otherwise in private civil infringement litigation.[43]

https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

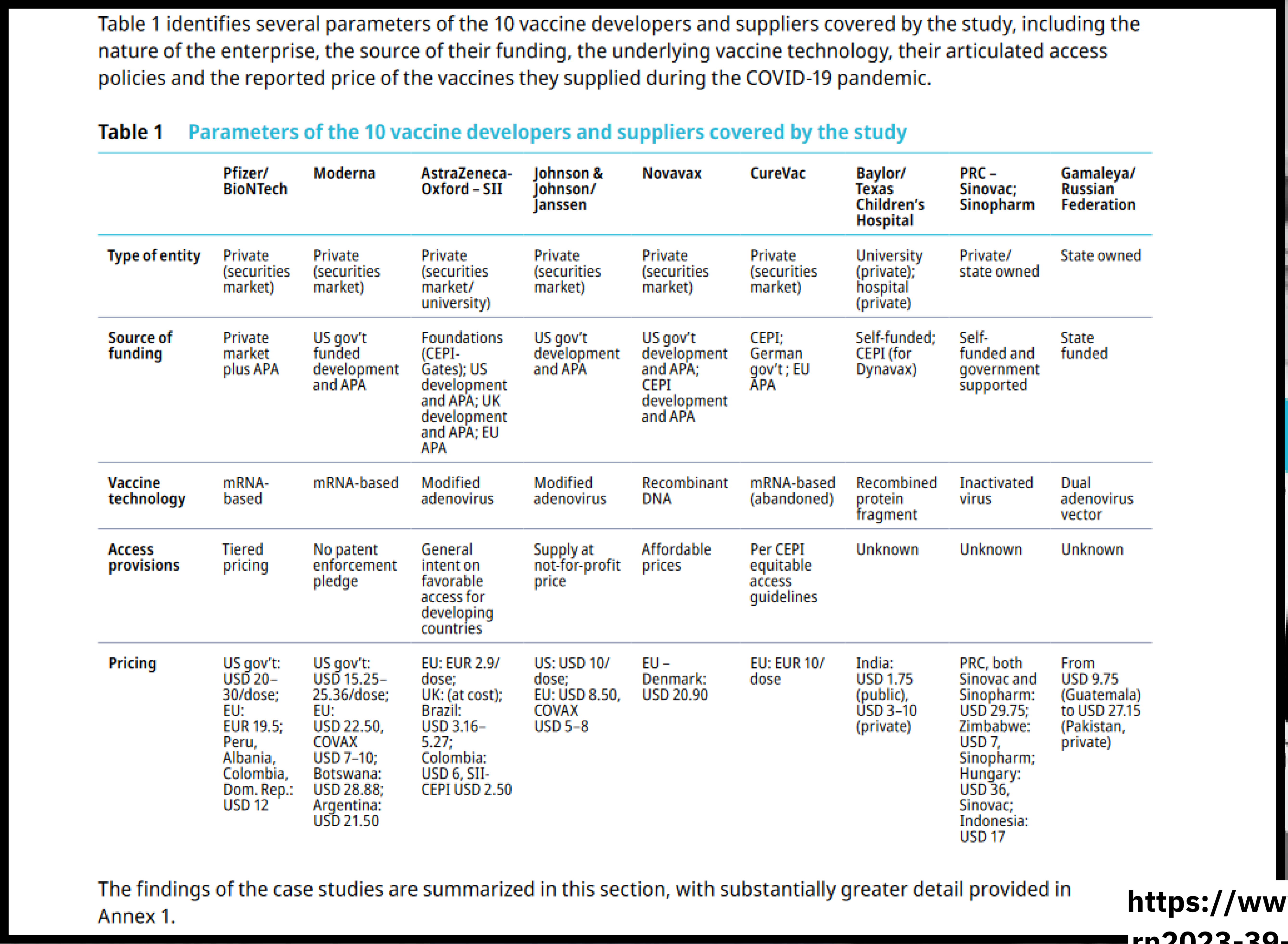
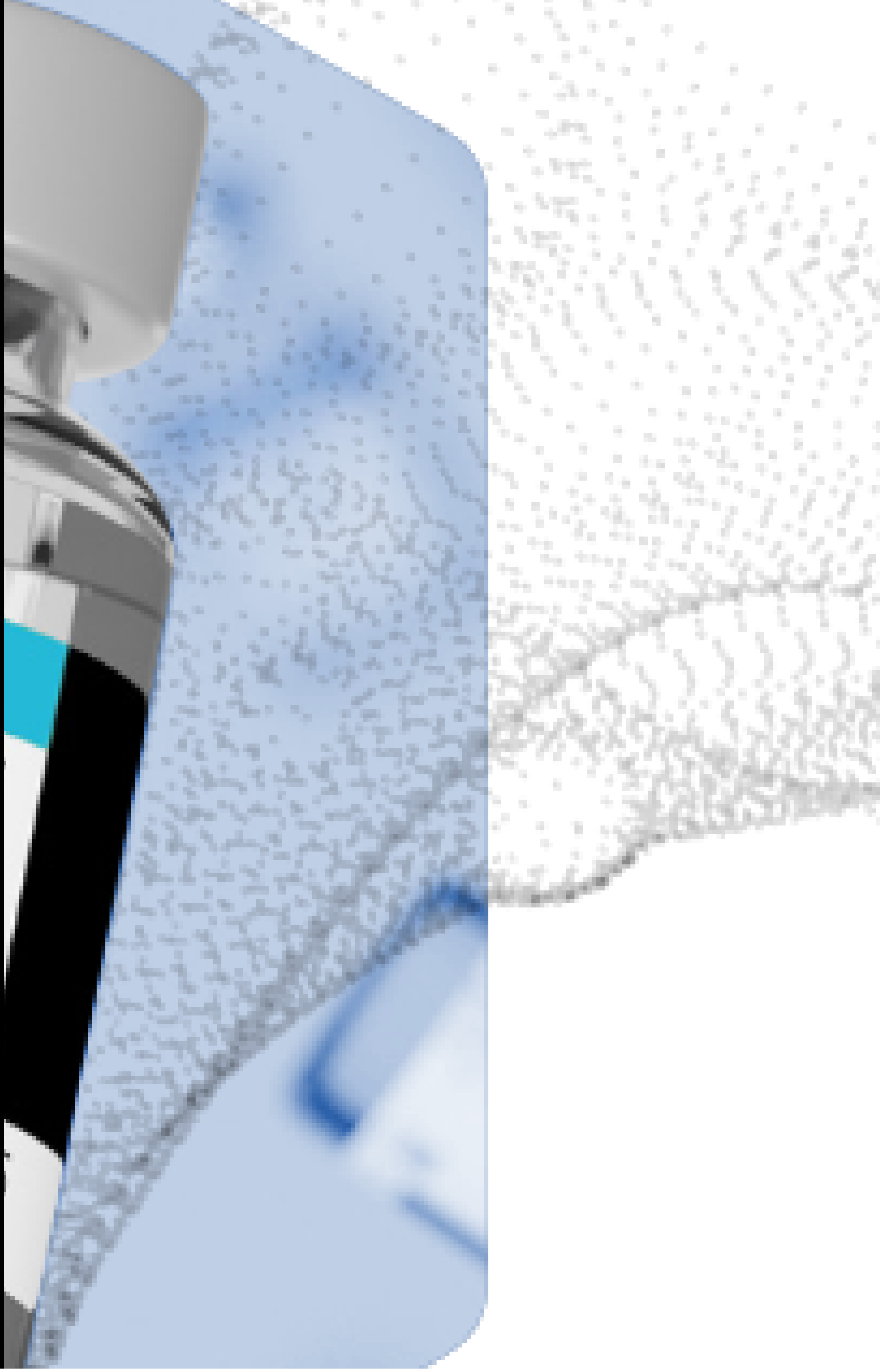


Table 1 identifies several parameters of the 10 vaccine developers and suppliers covered by the study, including the nature of the enterprise, the source of their funding, the underlying vaccine technology, their articulated access policies and the reported price of the vaccines they supplied during the COVID-19 pandemic.

Table 1 Parameters of the 10 vaccine developers and suppliers covered by the study

	Pfizer/ BioNTech	Moderna	AstraZeneca-Oxford – SII	Johnson & Johnson/ Janssen	Novavax	CureVac	Baylor/ Texas Children's Hospital	PRC – Sinovac; Sinopharm	Gamaleya/ Russian Federation
Type of entity	Private (securities market)	Private (securities market)	Private (securities market/ university)	Private (securities market)	Private (securities market)	Private (securities market)	University (private); hospital (private)	Private/ state owned	State owned
Source of funding	Private market plus APA	US gov't funded development and APA	Foundations (CEPI-Gates); US development and APA; UK development and APA; EU APA	US gov't development and APA	US gov't development and APA; CEPI development and APA	CEPI; German gov't ; EU APA	Self-funded; CEPI (for Dynavax)	Self-funded and government supported	State funded
Vaccine technology	mRNA-based	mRNA-based	Modified adenovirus	Modified adenovirus	Recombinant DNA	mRNA-based (abandoned)	Recombined protein fragment	Inactivated virus	Dual adenovirus vector
Access provisions	Tiered pricing	No patent enforcement pledge	General intent on favorable access for developing countries	Supply at not-for-profit price	Affordable prices	Per CEPI equitable access guidelines	Unknown	Unknown	Unknown
Pricing	US gov't: USD 20–30/dose; EU: EUR 19.5; Peru, Albania, Colombia, Dom. Rep.: USD 12	US gov't: USD 15.25–25.36/dose; EU: USD 22.50, COVAX USD 7–10; Botswana: USD 28.88; Argentina: USD 21.50	EU: EUR 2.9/ dose; UK: (at cost); Brazil: USD 3.16–5.27; Colombia: USD 6, SII-CEPI USD 2.50	US: USD 10/ dose; EU: USD 8.50, COVAX USD 5–8	EU – Denmark: USD 20.90	EU: EUR 10/ dose	India: USD 1.75 (public), USD 3–10 (private)	PRC, both Sinovac and Sinopharm: USD 29.75; Zimbabwe: USD 7, Sinopharm; Hungary: USD 36, Sinovac; Indonesia: USD 17	From USD 9.75 (Guatemala) to USD 27.15 (Pakistan, private)

The findings of the case studies are summarized in this section, with substantially greater detail provided in Annex 1.



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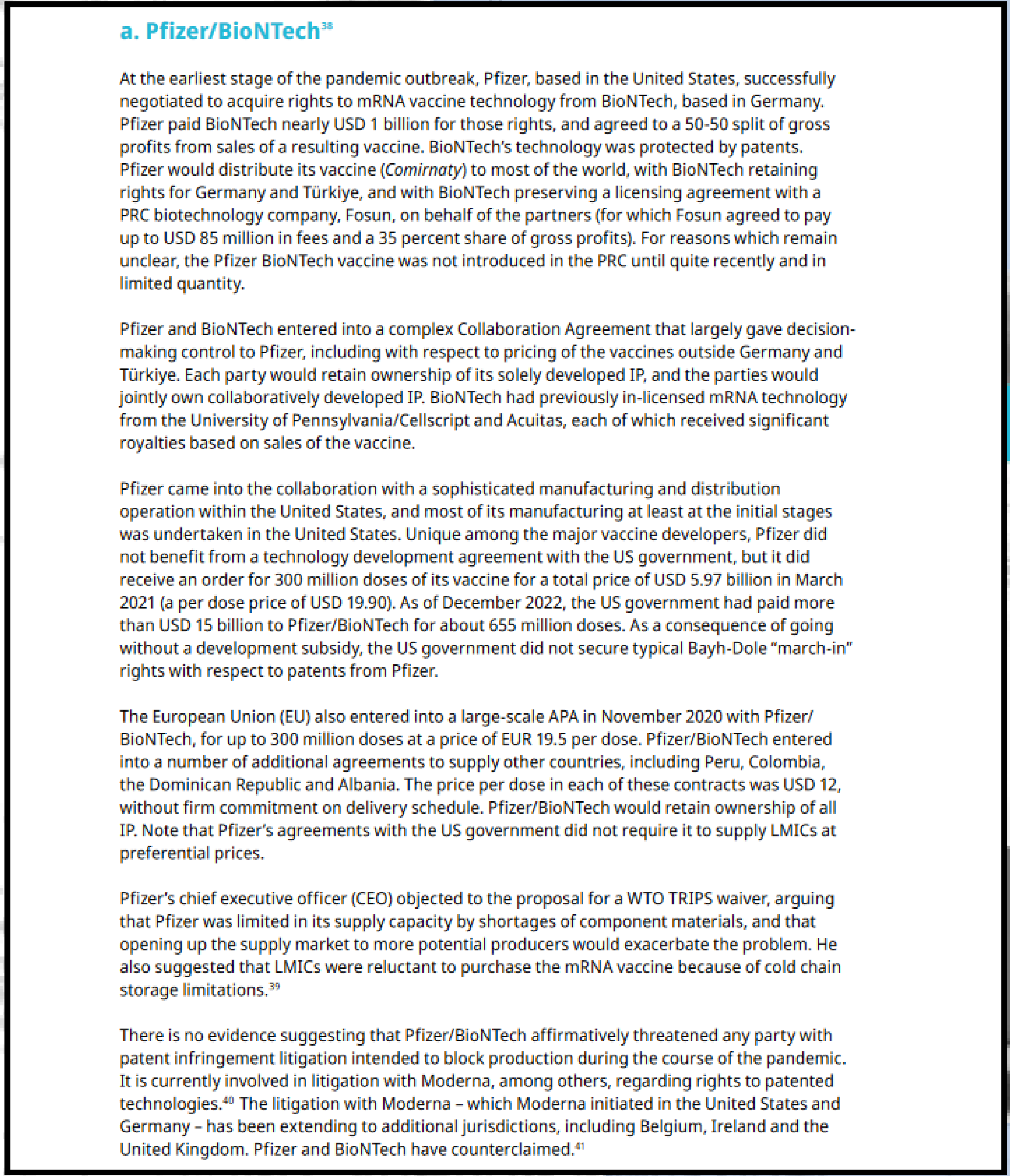

a. Pfizer/BioNTech[38]

At the earliest stage of the pandemic outbreak, Pfizer, based in the United States, successfully negotiated to acquire rights to mRNA vaccine technology from BioNTech, based in Germany. Pfizer paid BioNTech nearly USD 1 billion for those rights, and agreed to a 50-50 split of gross profits from sales of a resulting vaccine. BioNTech's technology was protected by patents. Pfizer would distribute its vaccine (*Comirnaty*) to most of the world, with BioNTech retaining rights for Germany and Türkiye, and with BioNTech preserving a licensing agreement with a PRC biotechnology company, Fosun, on behalf of the partners (for which Fosun agreed to pay up to USD 85 million in fees and a 35 percent share of gross profits). For reasons which remain unclear, the Pfizer BioNTech vaccine was not introduced in the PRC until quite recently and in limited quantity.

Pfizer and BioNTech entered into a complex Collaboration Agreement that largely gave decision-making control to Pfizer, including with respect to pricing of the vaccines outside Germany and Türkiye. Each party would retain ownership of its solely developed IP, and the parties would jointly own collaboratively developed IP. BioNTech had previously in-licensed mRNA technology from the University of Pennsylvania/Cellscript and Acuitas, each of which received significant royalties based on sales of the vaccine.

Pfizer came into the collaboration with a sophisticated manufacturing and distribution operation within the United States, and most of its manufacturing at least at the initial stages was undertaken in the United States. Unique among the major vaccine developers, Pfizer did not benefit from a technology development agreement with the US government, but it did receive an order for 300 million doses of its vaccine for a total price of USD 5.97 billion in March 2021 (a per dose price of USD 19.90). As of December 2022, the US government had paid more than USD 15 billion to Pfizer/BioNTech for about 655 million doses. As a consequence of going without a development subsidy, the US government did not secure typical Bayh-Dole "march-in" rights with respect to patents from Pfizer.

The European Union (EU) also entered into a large-scale APA in November 2020 with Pfizer/BioNTech, for up to 300 million doses at a price of EUR 19.5 per dose. Pfizer/BioNTech entered into a number of additional agreements to supply other countries, including Peru, Colombia, the Dominican Republic and Albania. The price per dose in each of these contracts was USD 12, without firm commitment on delivery schedule. Pfizer/BioNTech would retain ownership of all IP. Note that Pfizer's agreements with the US government did not require it to supply LMICs at preferential prices.

Pfizer's chief executive officer (CEO) objected to the proposal for a WTO TRIPS waiver, arguing that Pfizer was limited in its supply capacity by shortages of component materials, and that opening up the supply market to more potential producers would exacerbate the problem. He also suggested that LMICs were reluctant to purchase the mRNA vaccine because of cold chain storage limitations.[39]

There is no evidence suggesting that Pfizer/BioNTech affirmatively threatened any party with patent infringement litigation intended to block production during the course of the pandemic. It is currently involved in litigation with Moderna, among others, regarding rights to patented technologies.[40] The litigation with Moderna – which Moderna initiated in the United States and Germany – has been extending to additional jurisdictions, including Belgium, Ireland and the United Kingdom. Pfizer and BioNTech have counterclaimed.[41]

https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

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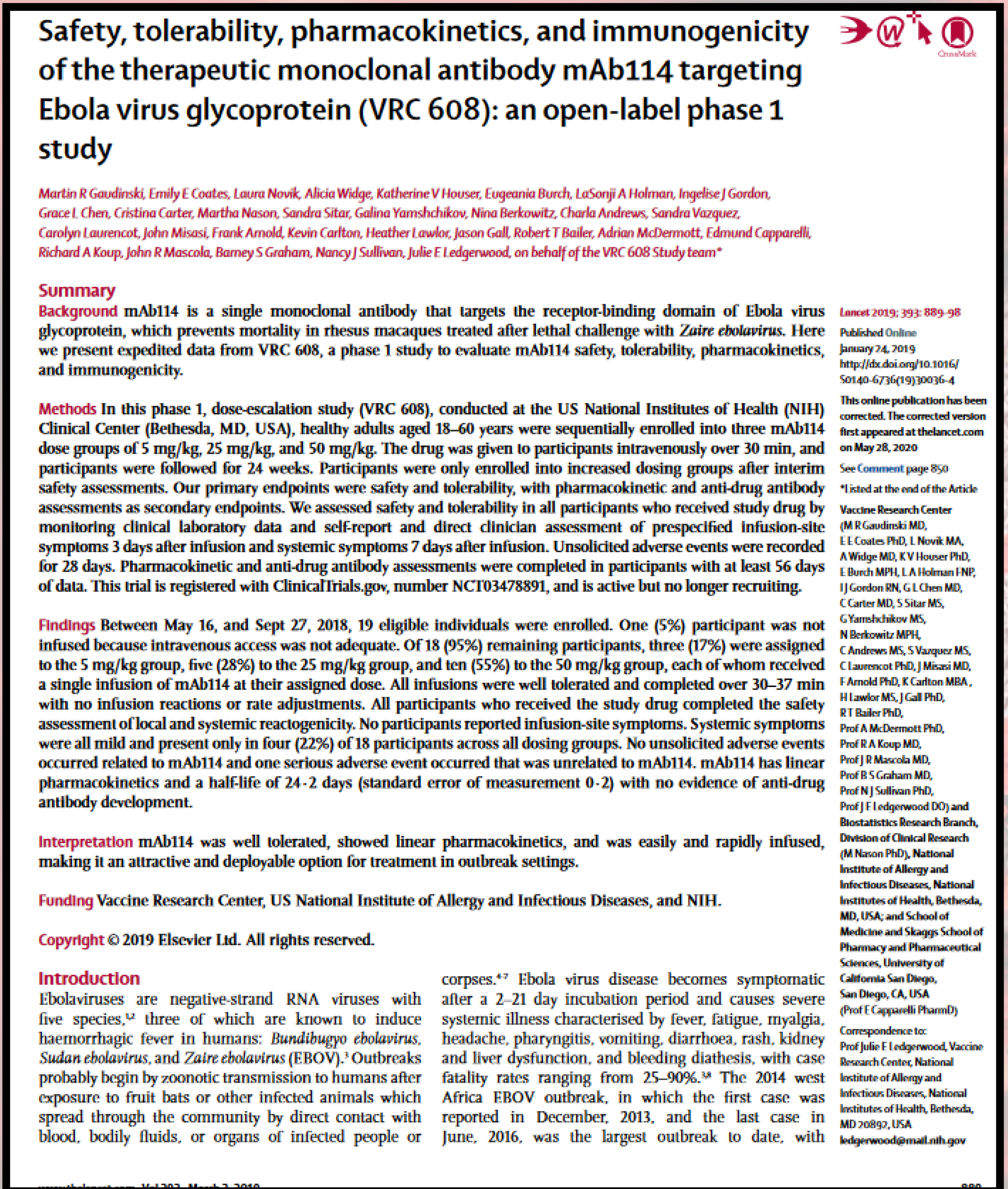

Safety, tolerability, pharmacokinetics, and immunogenicity of the therapeutic monoclonal antibody mAb114 targeting Ebola virus glycoprotein (VRC 608): an open-label phase 1 study

*Martin R Gaudinski, Emily E Coates, Laura Novik, Alicia Widge, Katherine V Houser, Eugeania Burch, LaSonji A Holman, Ingelise J Gordon, Grace L Chen, Cristina Carter, Martha Nason, Sandra Sitar, Galina Yamshchikov, Nina Berkowitz, Charla Andrews, Sandra Vazquez, Carolyn Laurencot, John Misasi, Frank Arnold, Kevin Carlton, Heather Lawlor, Jason Gall, Robert T Bailer, Adrian McDermott, Edmund Capparelli, Richard A Koup, John R Mascola, Barney S Graham, Nancy J Sullivan, Julie E Ledgerwood, on behalf of the VRC 608 Study team**

Summary

Background mAb114 is a single monoclonal antibody that targets the receptor-binding domain of Ebola virus glycoprotein, which prevents mortality in rhesus macaques treated after lethal challenge with *Zaire ebolavirus*. Here we present expedited data from VRC 608, a phase 1 study to evaluate mAb114 safety, tolerability, pharmacokinetics, and immunogenicity.

Methods In this phase 1, dose-escalation study (VRC 608), conducted at the US National Institutes of Health (NIH) Clinical Center (Bethesda, MD, USA), healthy adults aged 18–60 years were sequentially enrolled into three mAb114 dose groups of 5 mg/kg, 25 mg/kg, and 50 mg/kg. The drug was given to participants intravenously over 30 min, and participants were followed for 24 weeks. Participants were only enrolled into increased dosing groups after interim safety assessments. Our primary endpoints were safety and tolerability, with pharmacokinetic and anti-drug antibody assessments as secondary endpoints. We assessed safety and tolerability in all participants who received study drug by monitoring clinical laboratory data and self-report and direct clinician assessment of prespecified infusion-site symptoms 3 days after infusion and systemic symptoms 7 days after infusion. Unsolicited adverse events were recorded for 28 days. Pharmacokinetic and anti-drug antibody assessments were completed in participants with at least 56 days of data. This trial is registered with ClinicalTrials.gov, number NCT03478891, and is active but no longer recruiting.

Findings Between May 16, and Sept 27, 2018, 19 eligible individuals were enrolled. One (5%) participant was not infused because intravenous access was not adequate. Of 18 (95%) remaining participants, three (17%) were assigned to the 5 mg/kg group, five (28%) to the 25 mg/kg group, and ten (55%) to the 50 mg/kg group, each of whom received a single infusion of mAb114 at their assigned dose. All infusions were well tolerated and completed over 30–37 min with no infusion reactions or rate adjustments. All participants who received the study drug completed the safety assessment of local and systemic reactogenicity. No participants reported infusion-site symptoms. Systemic symptoms were all mild and present only in four (22%) of 18 participants across all dosing groups. No unsolicited adverse events occurred related to mAb114 and one serious adverse event occurred that was unrelated to mAb114. mAb114 has linear pharmacokinetics and a half-life of 24·2 days (standard error of measurement 0·2) with no evidence of anti-drug antibody development.

Interpretation mAb114 was well tolerated, showed linear pharmacokinetics, and was easily and rapidly infused, making it an attractive and deployable option for treatment in outbreak settings.

Funding Vaccine Research Center, US National Institute of Allergy and Infectious Diseases, and NIH.

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Introduction

Ebolaviruses are negative-strand RNA viruses with five species,[1,2] three of which are known to induce haemorrhagic fever in humans: *Bundibugyo ebolavirus*, *Sudan ebolavirus*, and *Zaire ebolavirus* (EBOV).[3] Outbreaks probably begin by zoonotic transmission to humans after exposure to fruit bats or other infected animals which spread through the community by direct contact with blood, bodily fluids, or organs of infected people or corpses.[4–7] Ebola virus disease becomes symptomatic after a 2–21 day incubation period and causes severe systemic illness characterised by fever, fatigue, myalgia, headache, pharyngitis, vomiting, diarrhoea, rash, kidney and liver dysfunction, and bleeding diathesis, with case fatality rates ranging from 25–90%.[3,8] The 2014 west Africa EBOV outbreak, in which the first case was reported in December, 2013, and the last case in June, 2016, was the largest outbreak to date, with

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This online publication has been corrected. The corrected version first appeared at thelancet.com on May 28, 2020

See Comment page 850

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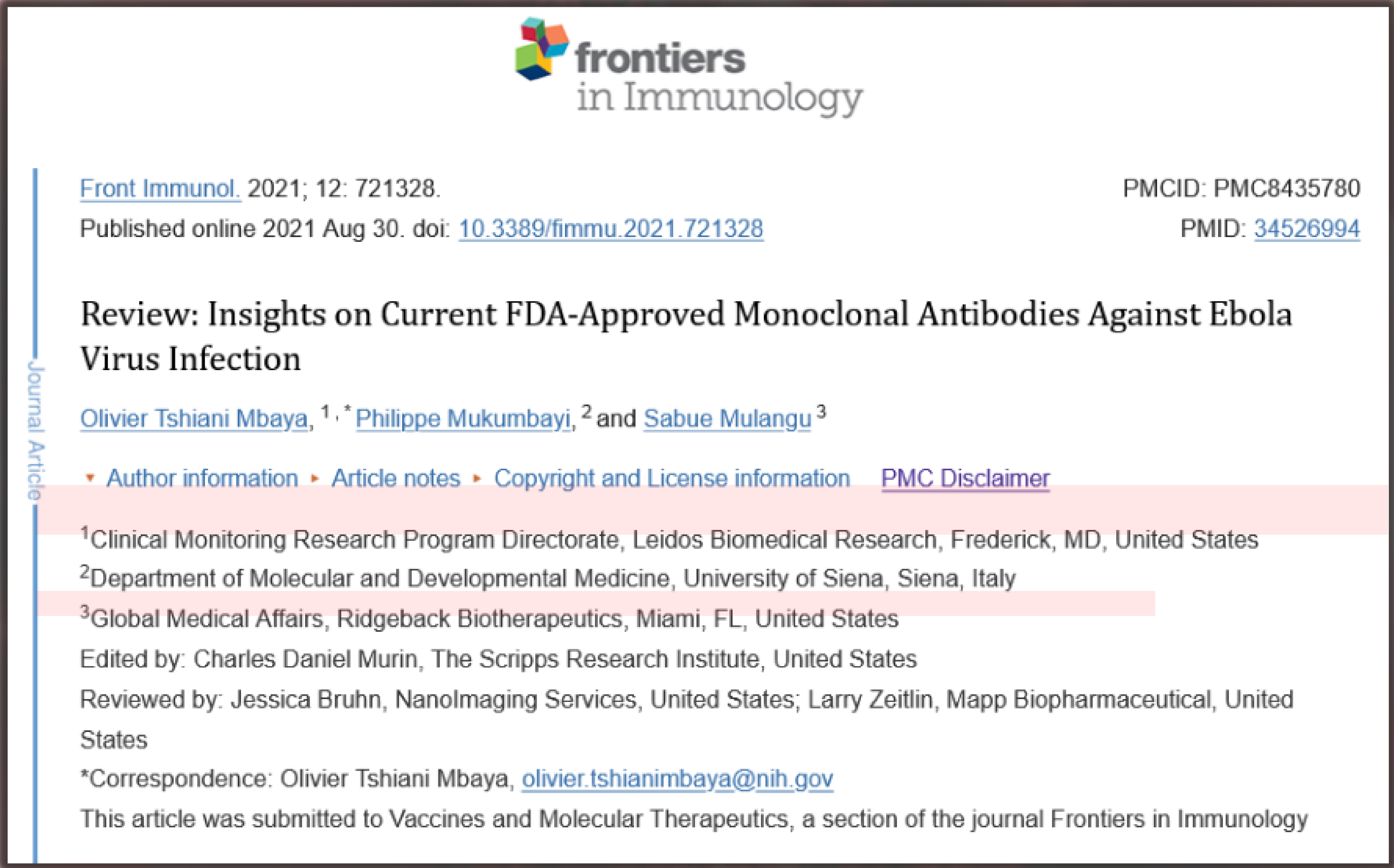

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Review: Insights on Current FDA-Approved Monoclonal Antibodies Against Ebola Virus Infection

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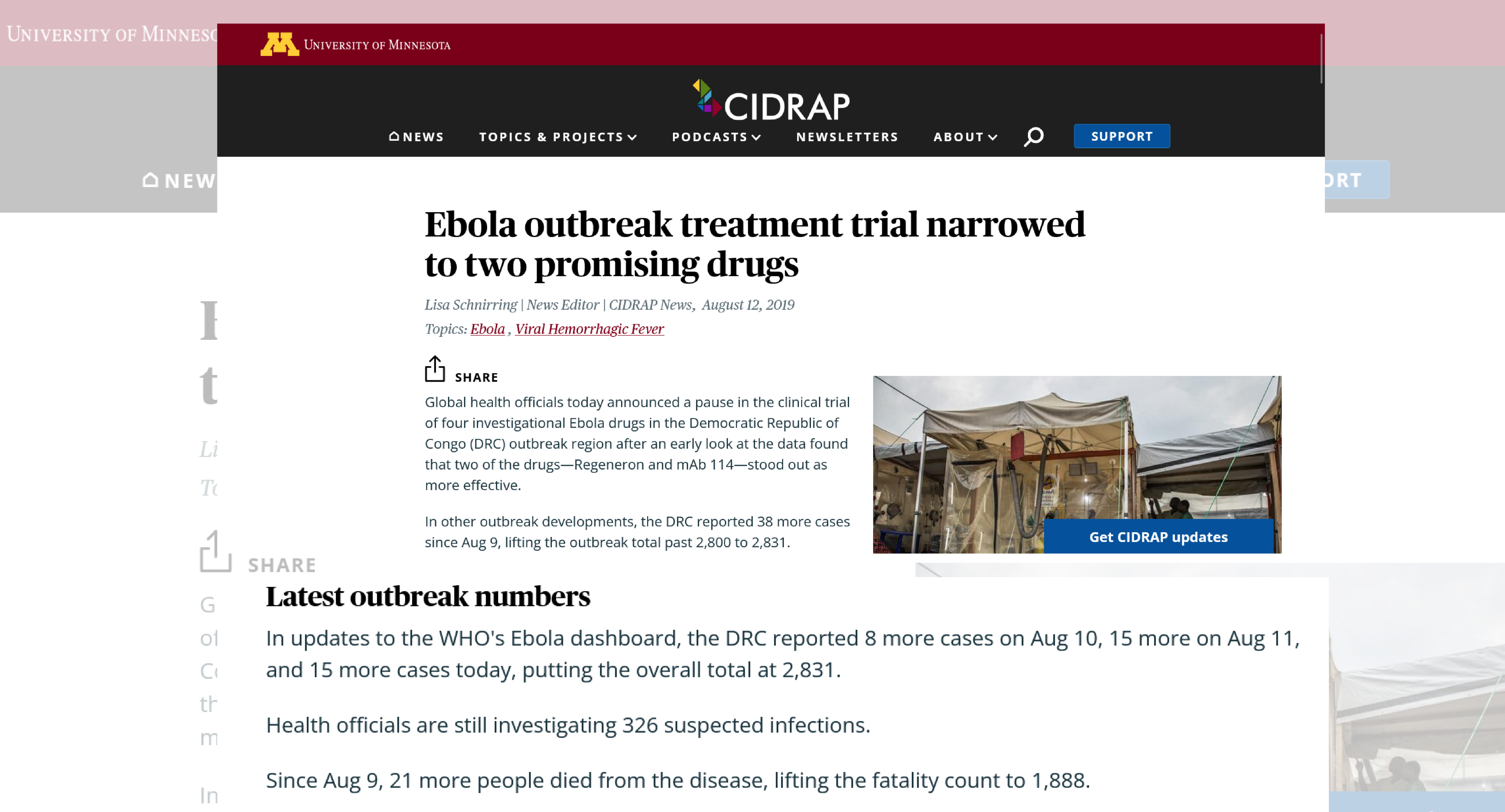


Ebola outbreak treatment trial narrowed to two promising drugs

Lisa Schnirring | News Editor | CIDRAP News, August 12, 2019

Topics: Ebola , Viral Hemorrhagic Fever

Global health officials today announced a pause in the clinical trial of four investigational Ebola drugs in the Democratic Republic of Congo (DRC) outbreak region after an early look at the data found that two of the drugs—Regeneron and mAb 114—stood out as more effective.

In other outbreak developments, the DRC reported 38 more cases since Aug 9, lifting the outbreak total past 2,800 to 2,831.

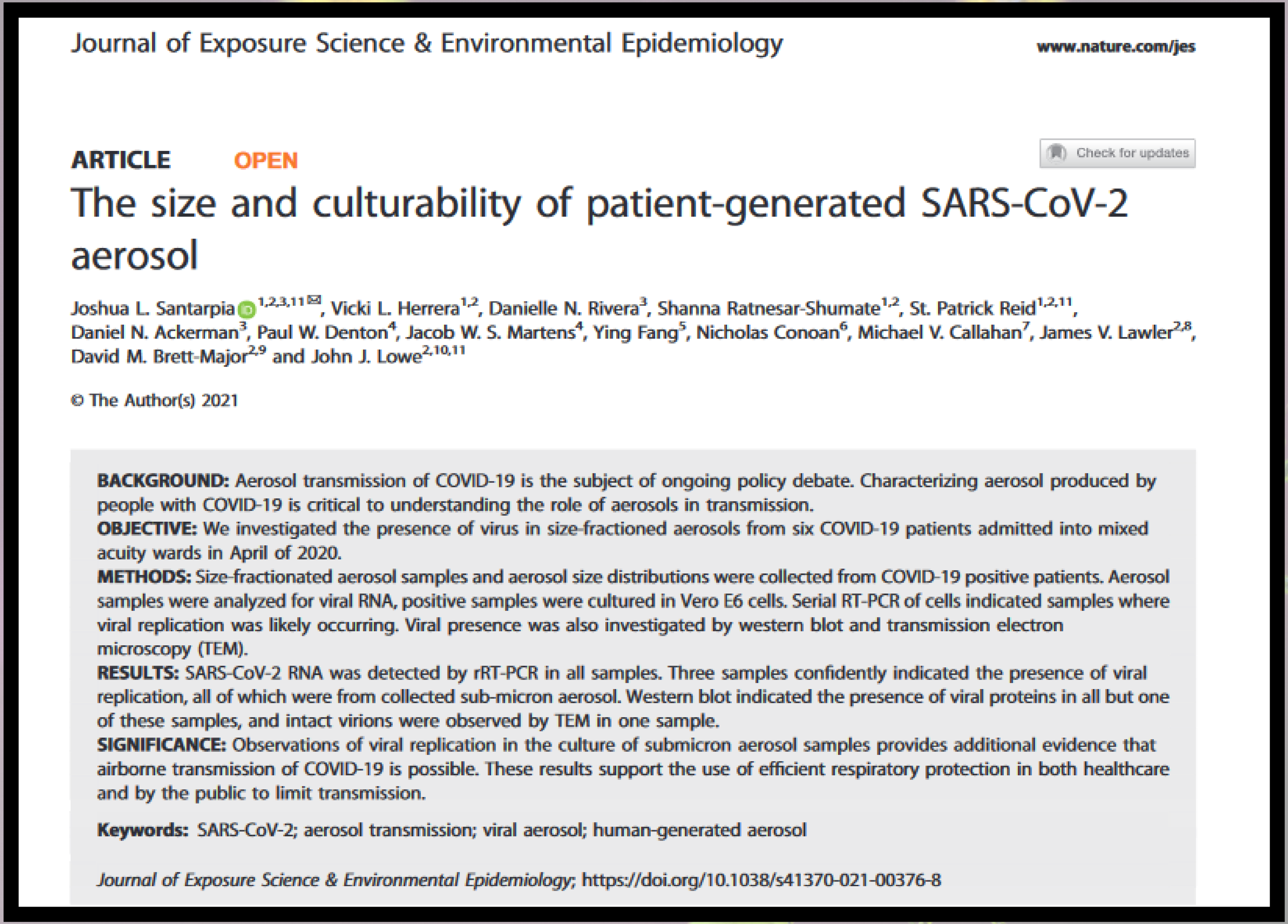
Latest outbreak numbers

In updates to the WHO's Ebola dashboard, the DRC reported 8 more cases on Aug 10, 15 more on Aug 11, and 15 more cases today, putting the overall total at 2,831.

Health officials are still investigating 326 suspected infections.

Since Aug 9, 21 more people died from the disease, lifting the fatality count to 1,888.

https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs



Journal of Exposure Science & Environmental Epidemiology www.nature.com/jes

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The size and culturability of patient-generated SARS-CoV-2 aerosol

Joshua L. Santarpia[1,2,3,11] ✉, Vicki L. Herrera[1,2], Danielle N. Rivera[3], Shanna Ratnesar-Shumate[1,2], St. Patrick Reid[1,2,11], Daniel N. Ackerman[3], Paul W. Denton[4], Jacob W. S. Martens[4], Ying Fang[5], Nicholas Conoan[6], Michael V. Callahan[7], James V. Lawler[2,8], David M. Brett-Major[2,9] and John J. Lowe[2,10,11]

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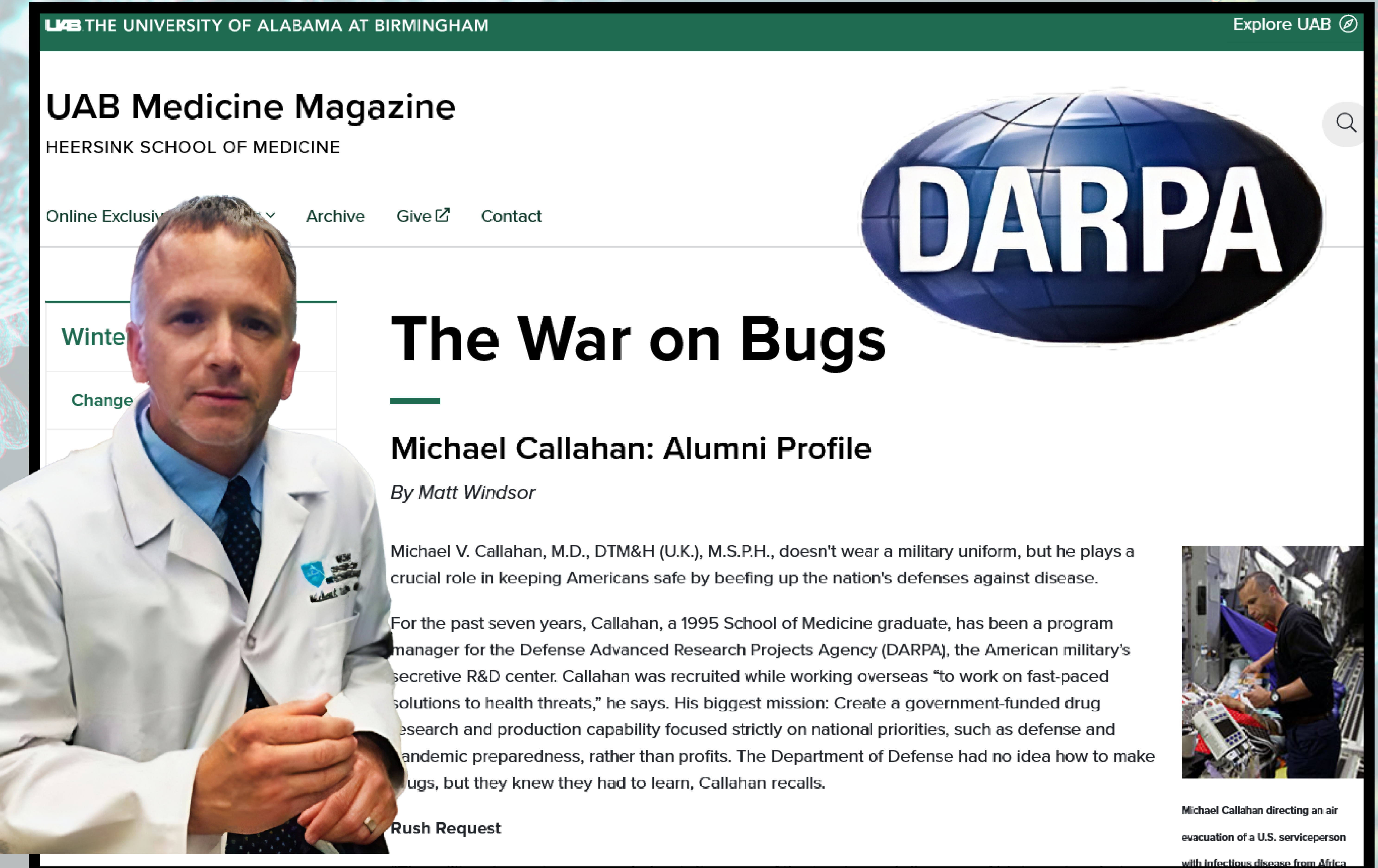
BACKGROUND: Aerosol transmission of COVID-19 is the subject of ongoing policy debate. Characterizing aerosol produced by people with COVID-19 is critical to understanding the role of aerosols in transmission.
OBJECTIVE: We investigated the presence of virus in size-fractioned aerosols from six COVID-19 patients admitted into mixed acuity wards in April of 2020.
METHODS: Size-fractionated aerosol samples and aerosol size distributions were collected from COVID-19 positive patients. Aerosol samples were analyzed for viral RNA, positive samples were cultured in Vero E6 cells. Serial RT-PCR of cells indicated samples where viral replication was likely occurring. Viral presence was also investigated by western blot and transmission electron microscopy (TEM).
RESULTS: SARS-CoV-2 RNA was detected by rRT-PCR in all samples. Three samples confidently indicated the presence of viral replication, all of which were from collected sub-micron aerosol. Western blot indicated the presence of viral proteins in all but one of these samples, and intact virions were observed by TEM in one sample.
SIGNIFICANCE: Observations of viral replication in the culture of submicron aerosol samples provides additional evidence that airborne transmission of COVID-19 is possible. These results support the use of efficient respiratory protection in both healthcare and by the public to limit transmission.

Keywords: SARS-CoV-2; aerosol transmission; viral aerosol; human-generated aerosol

Journal of Exposure Science & Environmental Epidemiology; https://doi.org/10.1038/s41370-021-00376-8

MICHAEL V. CALLAHAN



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The War on Bugs

Michael Callahan: Alumni Profile

By Matt Windsor

Michael V. Callahan, M.D., DTM&H (U.K.), M.S.P.H., doesn't wear a military uniform, but he plays a crucial role in keeping Americans safe by beefing up the nation's defenses against disease.

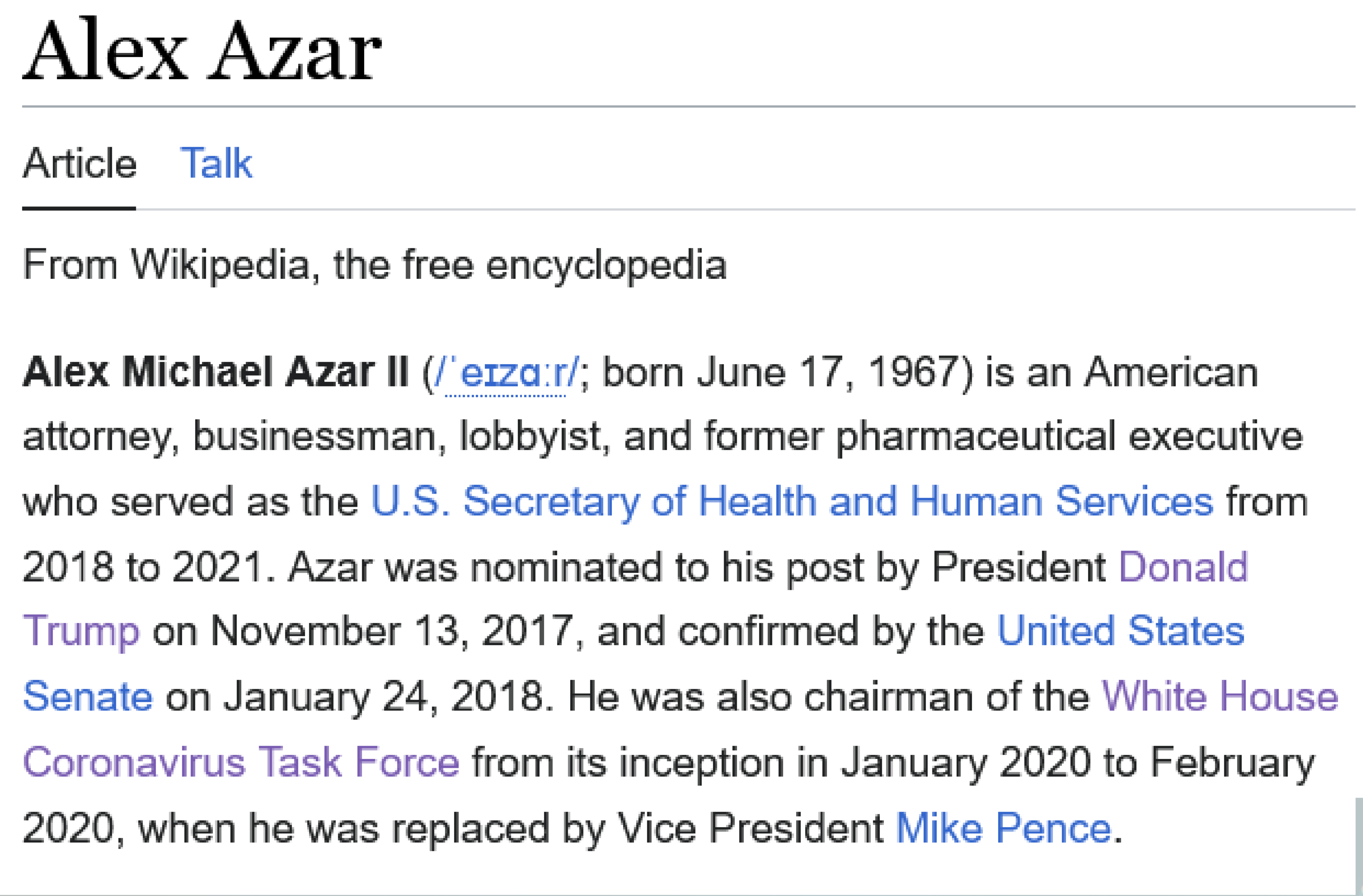
For the past seven years, Callahan, a 1995 School of Medicine graduate, has been a program manager for the Defense Advanced Research Projects Agency (DARPA), the American military's secretive R&D center. Callahan was recruited while working overseas "to work on fast-paced solutions to health threats," he says. His biggest mission: Create a government-funded drug esearch and production capability focused strictly on national priorities, such as defense and andemic preparedness, rather than profits. The Department of Defense had no idea how to make ugs, but they knew they had to learn, Callahan recalls.

Rush Request

Michael Callahan directing an air evacuation of a U.S. serviceperson with infectious disease from Africa

CENTRAL INTELLIGENCE AGENCY
UNITED STATES OF AMERICA

ALEX AZAR

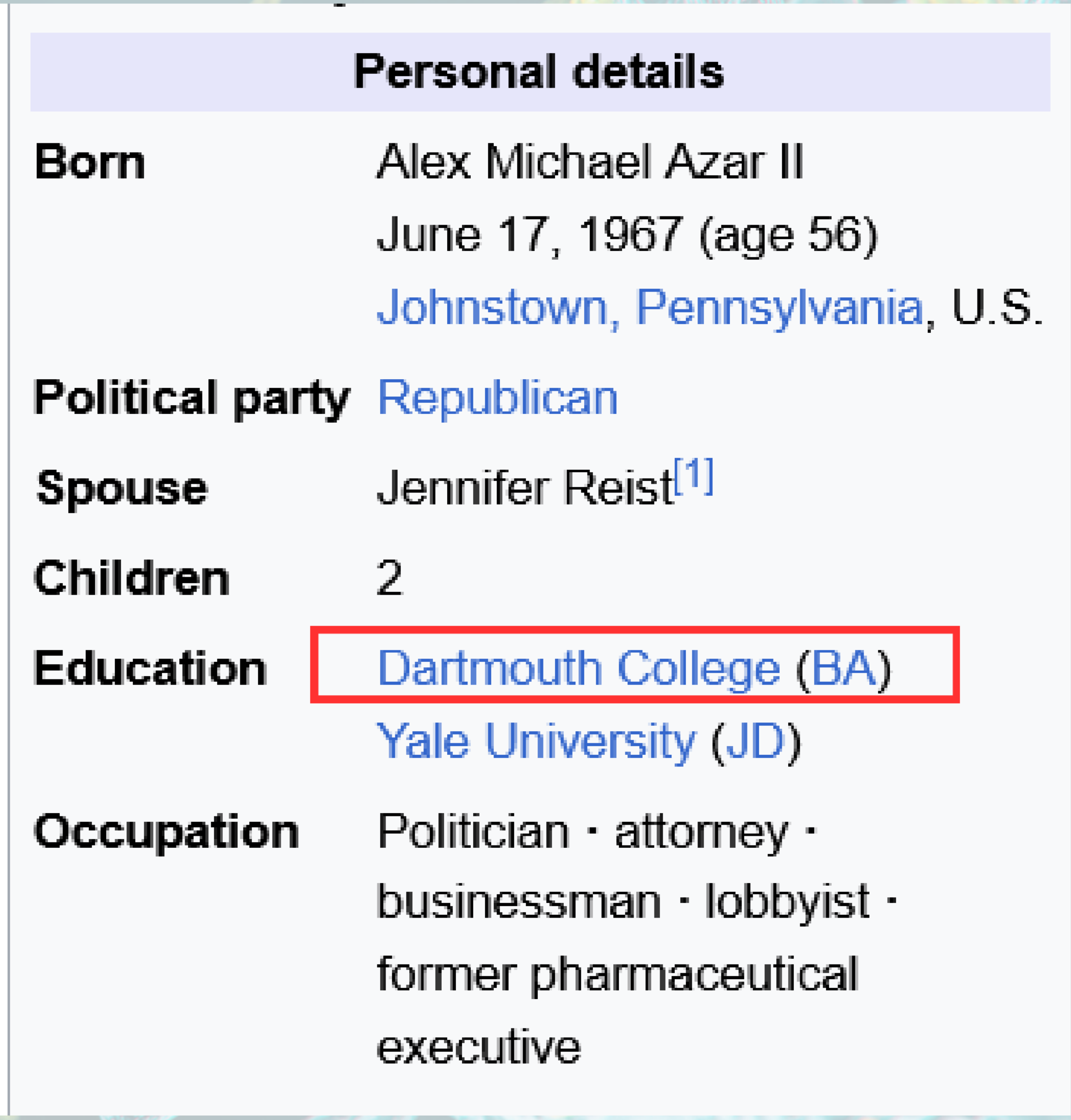


Alex Azar

Article Talk

From Wikipedia, the free encyclopedia

Alex Michael Azar II (/ˈeɪzɑːr/; born June 17, 1967) is an American attorney, businessman, lobbyist, and former pharmaceutical executive who served as the U.S. Secretary of Health and Human Services from 2018 to 2021. Azar was nominated to his post by President Donald Trump on November 13, 2017, and confirmed by the United States Senate on January 24, 2018. He was also chairman of the White House Coronavirus Task Force from its inception in January 2020 to February 2020, when he was replaced by Vice President Mike Pence.



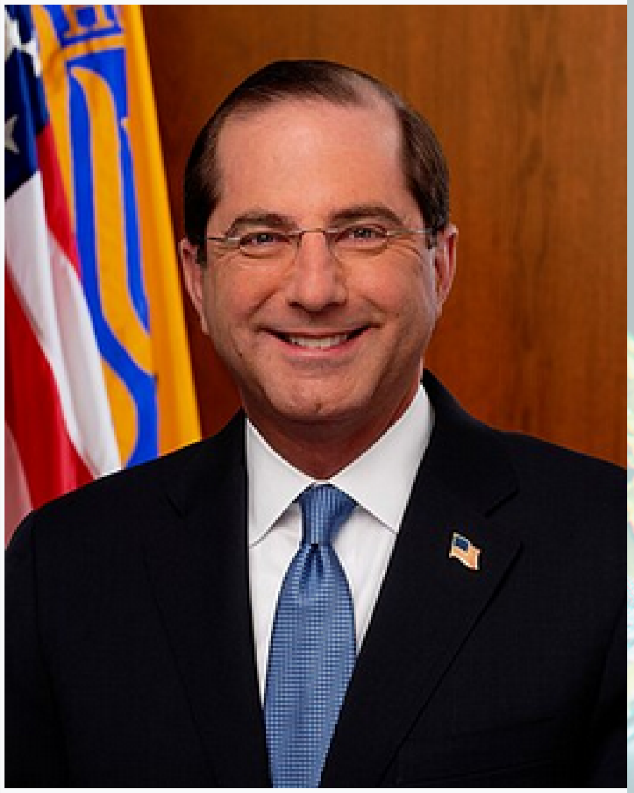
Personal details	
Born	Alex Michael Azar II June 17, 1967 (age 56) Johnstown, Pennsylvania, U.S.
Political party	Republican
Spouse	Jennifer Reist[1]
Children	2
Education	Dartmouth College (BA) Yale University (JD)
Occupation	Politician · attorney · businessman · lobbyist · former pharmaceutical executive

Alex Azar

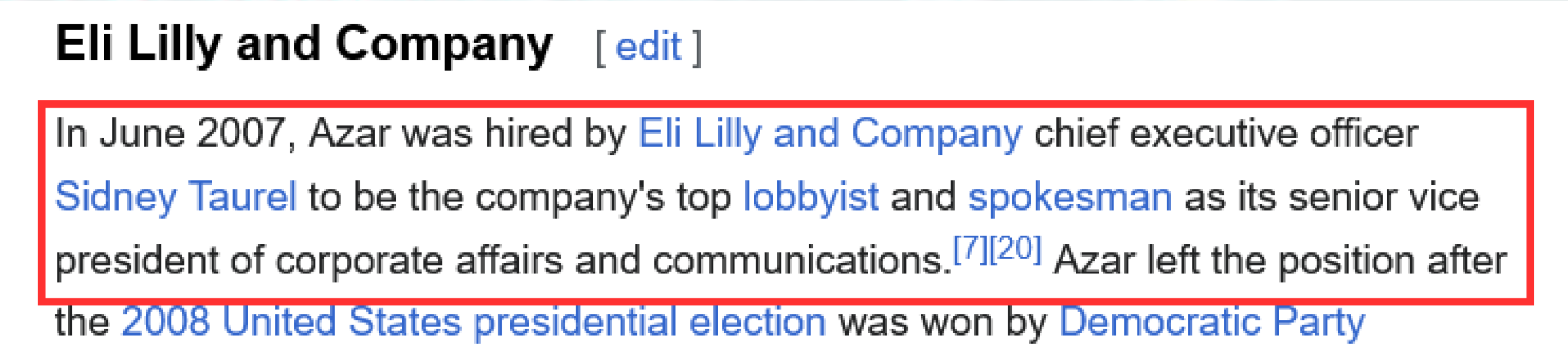
Official portrait, 2019

ALEX AZAR

Alex Azar

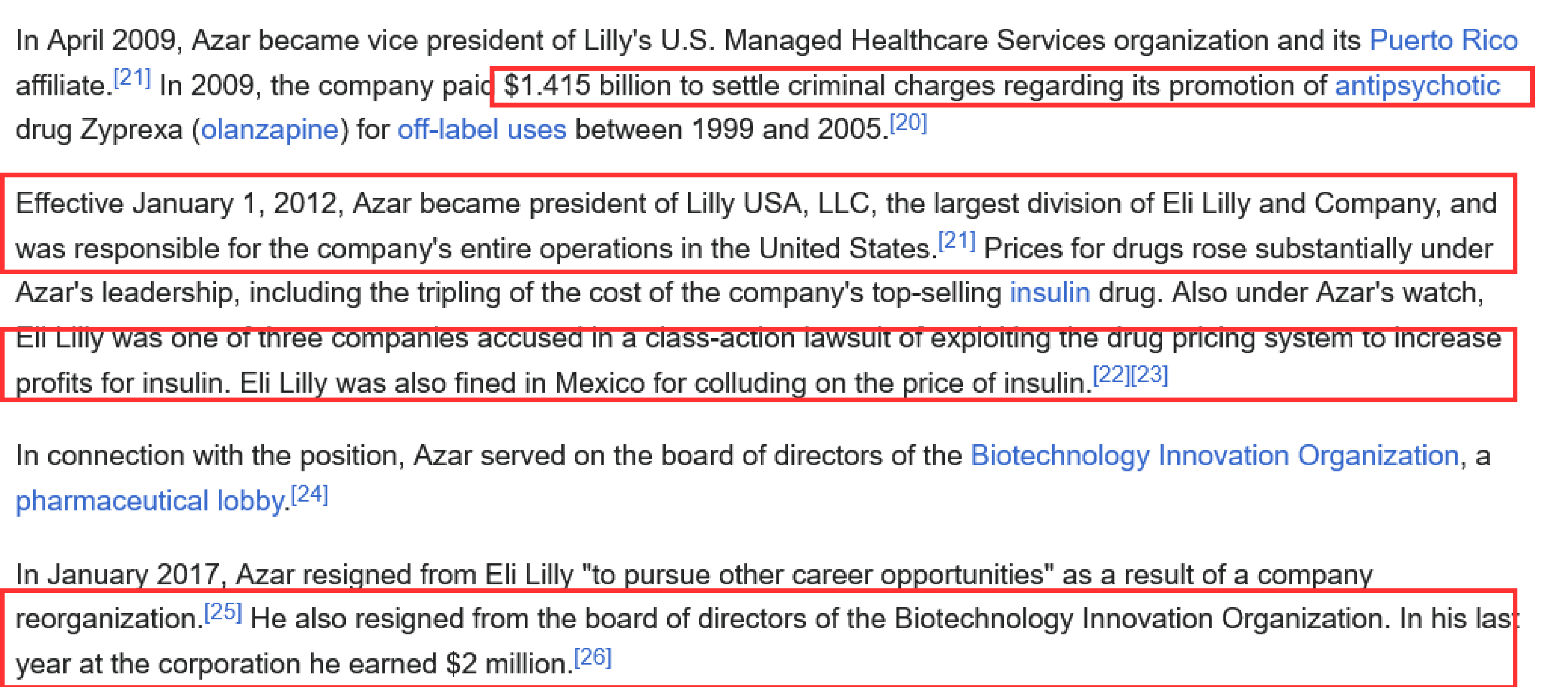


Official portrait, 2019



Eli Lilly and Company [edit]

In June 2007, Azar was hired by Eli Lilly and Company chief executive officer Sidney Taurel to be the company's top lobbyist and spokesman as its senior vice president of corporate affairs and communications.[7][20] Azar left the position after the 2008 United States presidential election was won by Democratic Party

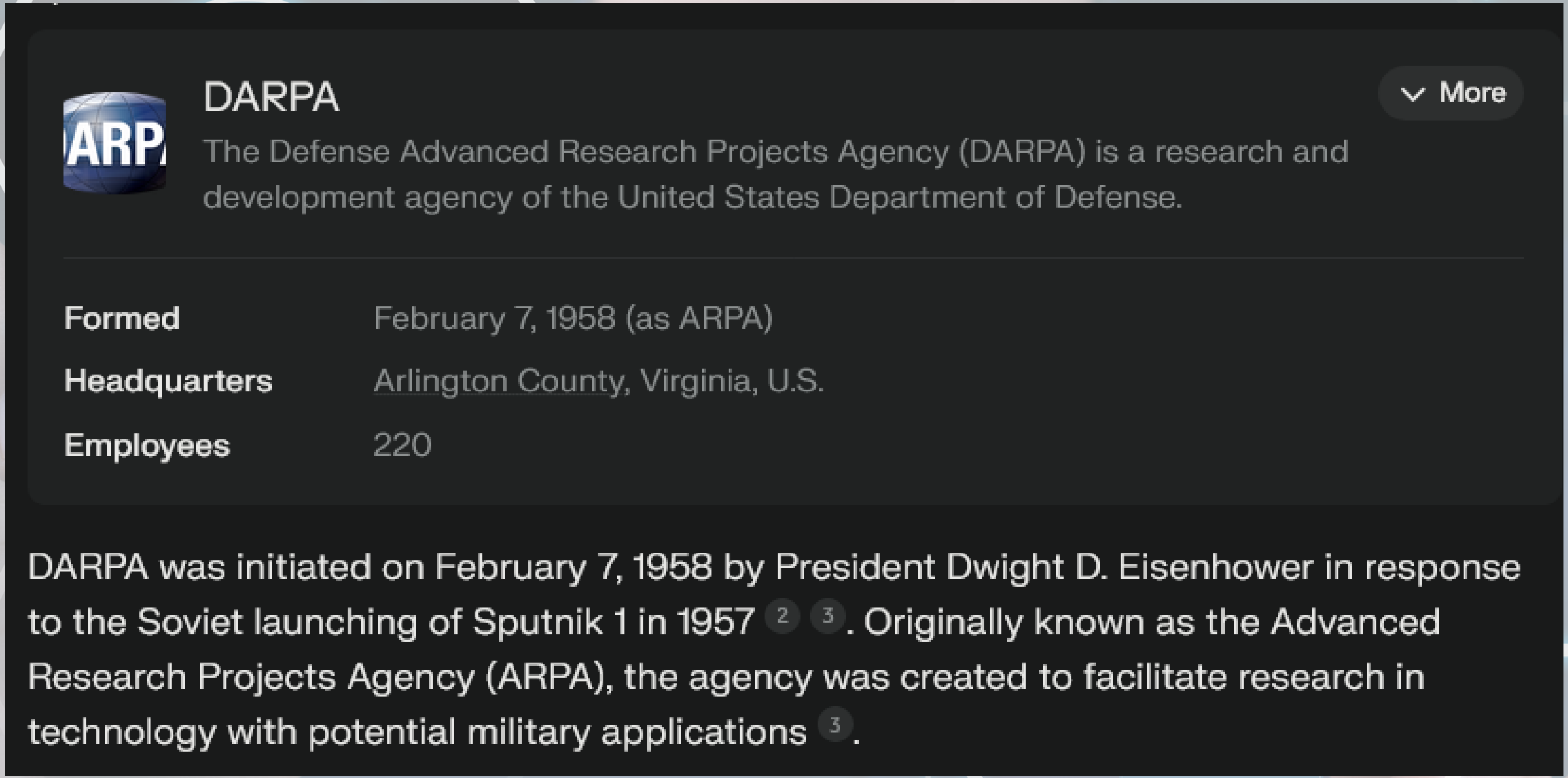


In April 2009, Azar became vice president of Lilly's U.S. Managed Healthcare Services organization and its Puerto Rico affiliate.[21] In 2009, the company paid $1.415 billion to settle criminal charges regarding its promotion of antipsychotic drug Zyprexa (olanzapine) for off-label uses between 1999 and 2005.[20]

Effective January 1, 2012, Azar became president of Lilly USA, LLC, the largest division of Eli Lilly and Company, and was responsible for the company's entire operations in the United States.[21] Prices for drugs rose substantially under Azar's leadership, including the tripling of the cost of the company's top-selling insulin drug. Also under Azar's watch, Eli Lilly was one of three companies accused in a class-action lawsuit of exploiting the drug pricing system to increase profits for insulin. Eli Lilly was also fined in Mexico for colluding on the price of insulin.[22][23]

In connection with the position, Azar served on the board of directors of the Biotechnology Innovation Organization, a pharmaceutical lobby.[24]

In January 2017, Azar resigned from Eli Lilly "to pursue other career opportunities" as a result of a company reorganization.[25] He also resigned from the board of directors of the Biotechnology Innovation Organization. In his last year at the corporation he earned $2 million.[26]

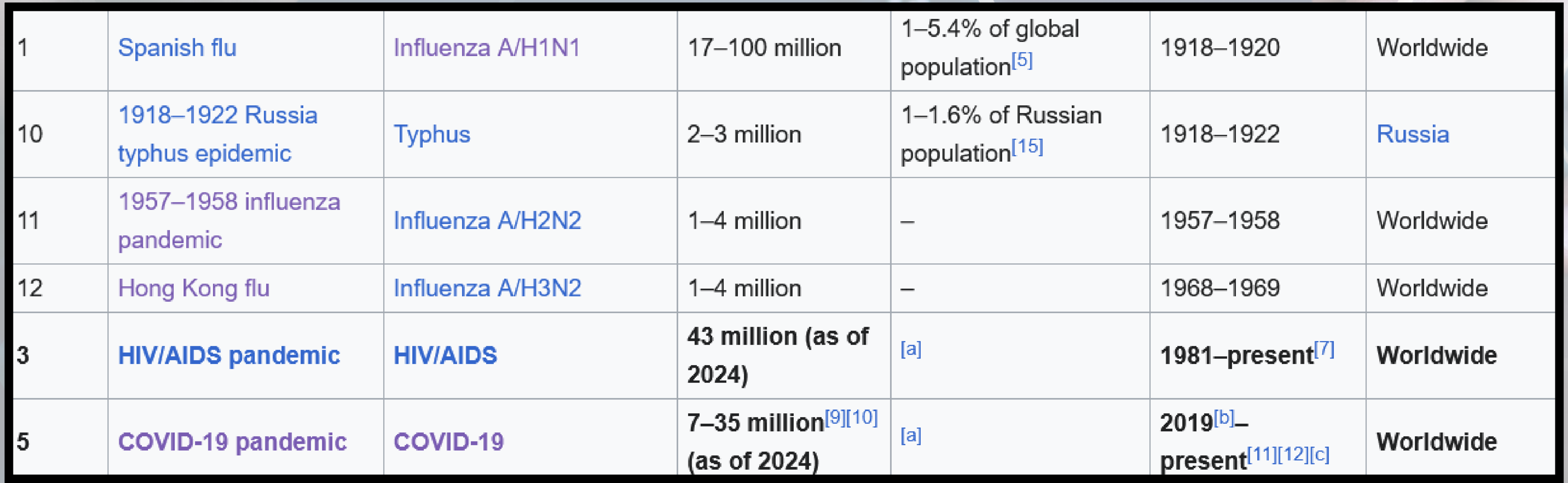


DARPA

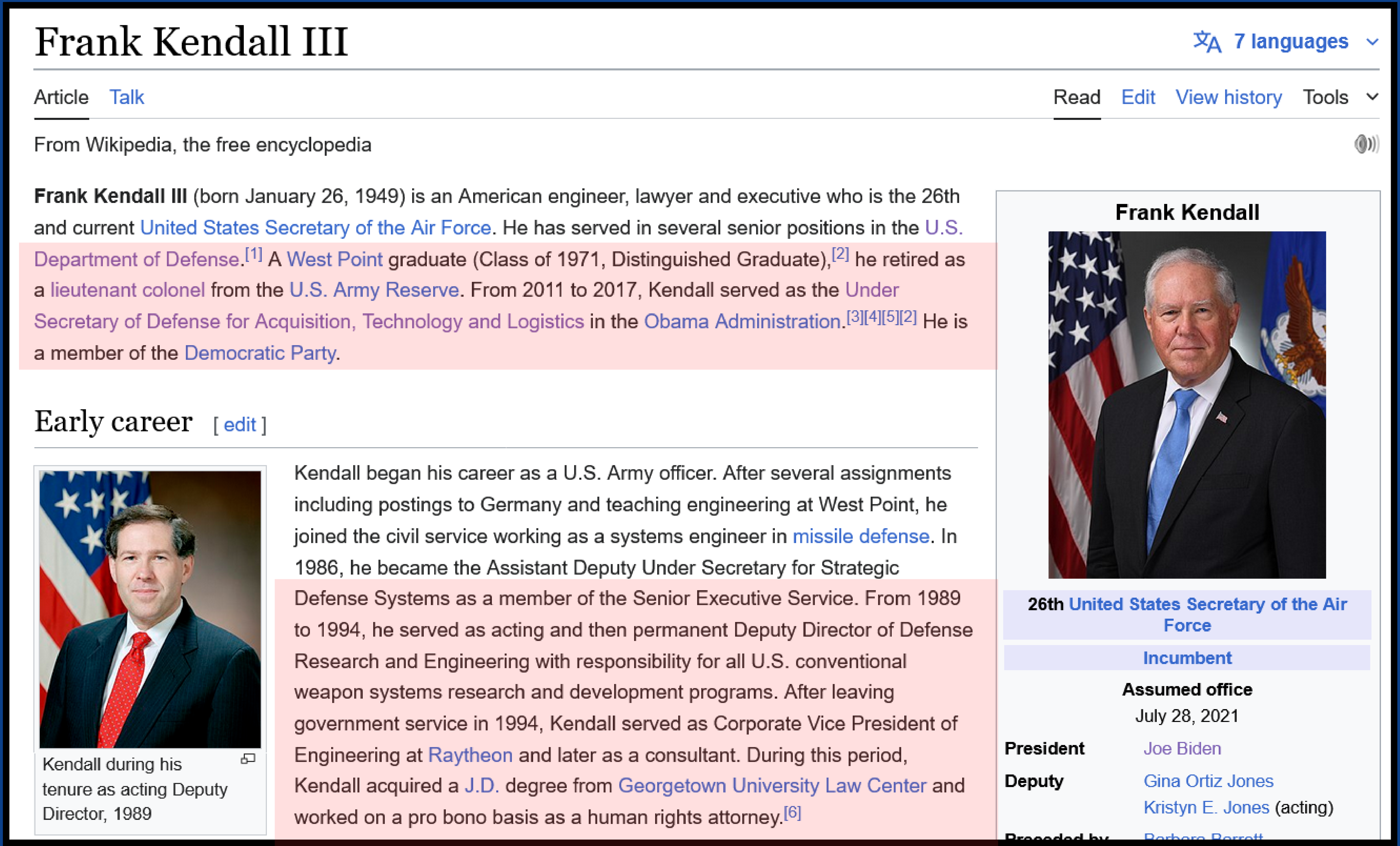
The Defense Advanced Research Projects Agency (DARPA) is a research and development agency of the United States Department of Defense.

Formed	February 7, 1958 (as ARPA)
Headquarters	Arlington County, Virginia, U.S.
Employees	220

DARPA was initiated on February 7, 1958 by President Dwight D. Eisenhower in response to the Soviet launching of Sputnik 1 in 1957 ② ③. Originally known as the Advanced Research Projects Agency (ARPA), the agency was created to facilitate research in technology with potential military applications ③.



1	Spanish flu	Influenza A/H1N1	17–100 million	1–5.4% of global population[5]	1918–1920	Worldwide
10	1918–1922 Russia typhus epidemic	Typhus	2–3 million	1–1.6% of Russian population[15]	1918–1922	Russia
11	1957–1958 influenza pandemic	Influenza A/H2N2	1–4 million	–	1957–1958	Worldwide
12	Hong Kong flu	Influenza A/H3N2	1–4 million	–	1968–1969	Worldwide
3	**HIV/AIDS pandemic**	**HIV/AIDS**	**43 million (as of 2024)**	[a]	**1981–present**[7]	**Worldwide**
5	**COVID-19 pandemic**	**COVID-19**	**7–35 million**[9][10] **(as of 2024)**	[a]	**2019**[b]**–present**[11][12][c]	**Worldwide**



Frank Kendall III

From Wikipedia, the free encyclopedia

Frank Kendall III (born January 26, 1949) is an American engineer, lawyer and executive who is the 26th and current United States Secretary of the Air Force. He has served in several senior positions in the U.S. Department of Defense.[1] A West Point graduate (Class of 1971, Distinguished Graduate),[2] he retired as a lieutenant colonel from the U.S. Army Reserve. From 2011 to 2017, Kendall served as the Under Secretary of Defense for Acquisition, Technology and Logistics in the Obama Administration.[3][4][5][2] He is a member of the Democratic Party.

Early career [edit]

Kendall during his tenure as acting Deputy Director, 1989

Kendall began his career as a U.S. Army officer. After several assignments including postings to Germany and teaching engineering at West Point, he joined the civil service working as a systems engineer in missile defense. In 1986, he became the Assistant Deputy Under Secretary for Strategic Defense Systems as a member of the Senior Executive Service. From 1989 to 1994, he served as acting and then permanent Deputy Director of Defense Research and Engineering with responsibility for all U.S. conventional weapon systems research and development programs. After leaving government service in 1994, Kendall served as Corporate Vice President of Engineering at Raytheon and later as a consultant. During this period, Kendall acquired a J.D. degree from Georgetown University Law Center and worked on a pro bono basis as a human rights attorney.[6]

Frank Kendall

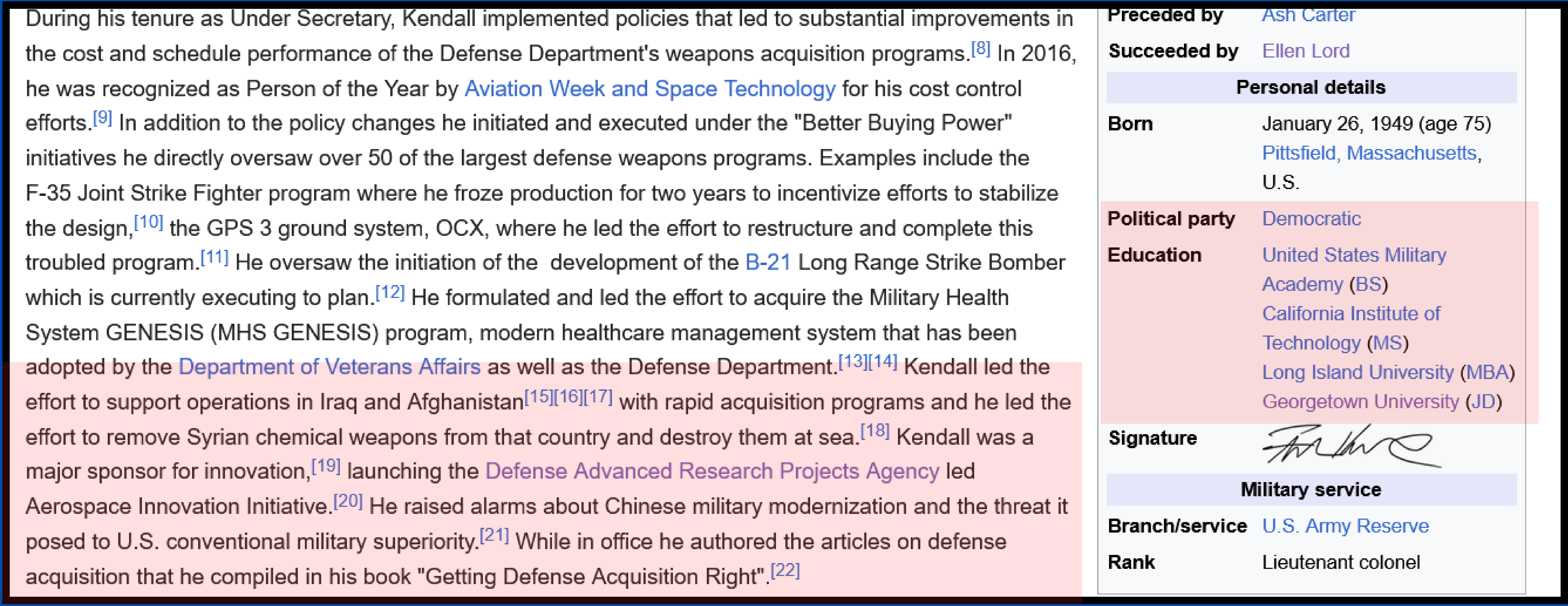
26th United States Secretary of the Air Force

Incumbent

Assumed office
July 28, 2021

President	Joe Biden
Deputy	Gina Ortiz Jones Kristyn E. Jones (acting)
Preceded by	Barbara Barrett

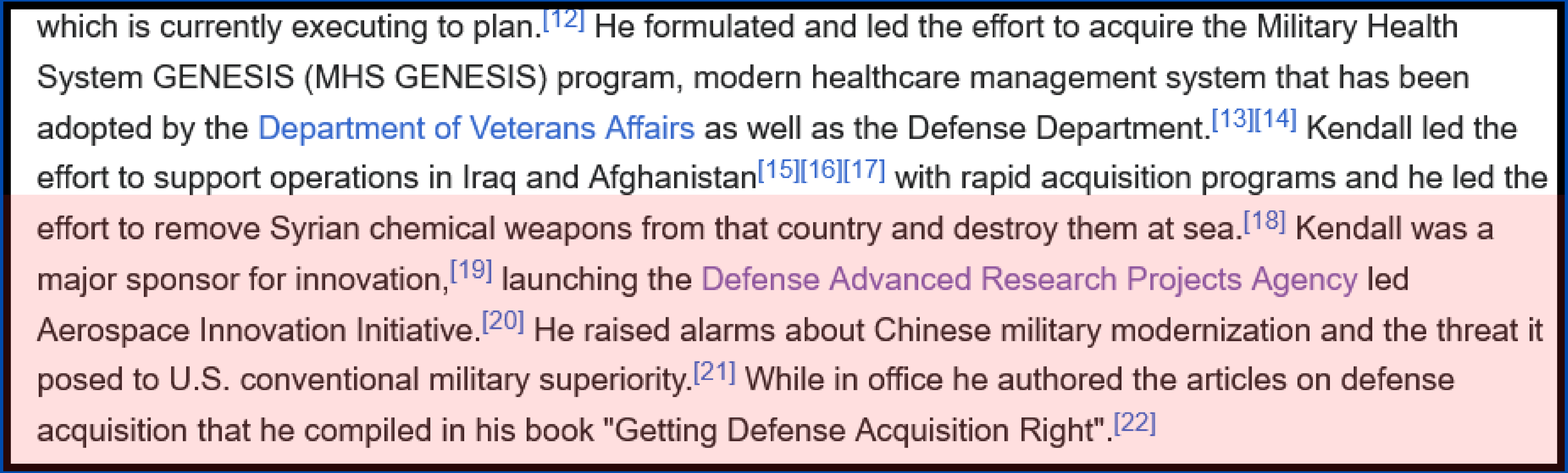
Frank Kendall III



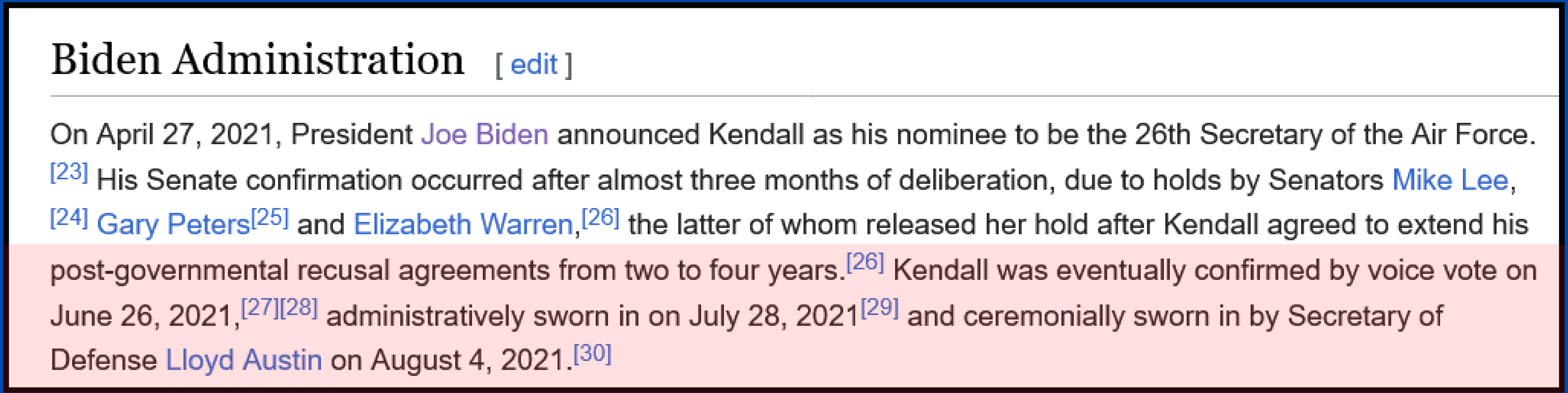
During his tenure as Under Secretary, Kendall implemented policies that led to substantial improvements in the cost and schedule performance of the Defense Department's weapons acquisition programs.[8] In 2016, he was recognized as Person of the Year by Aviation Week and Space Technology for his cost control efforts.[9] In addition to the policy changes he initiated and executed under the "Better Buying Power" initiatives he directly oversaw over 50 of the largest defense weapons programs. Examples include the F-35 Joint Strike Fighter program where he froze production for two years to incentivize efforts to stabilize the design,[10] the GPS 3 ground system, OCX, where he led the effort to restructure and complete this troubled program.[11] He oversaw the initiation of the development of the B-21 Long Range Strike Bomber which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]

Preceded by	Ash Carter
Succeeded by	Ellen Lord
Personal details	
Born	January 26, 1949 (age 75) Pittsfield, Massachusetts, U.S.
Political party	Democratic
Education	United States Military Academy (BS) California Institute of Technology (MS) Long Island University (MBA) Georgetown University (JD)
Signature	
Military service	
Branch/service	U.S. Army Reserve
Rank	Lieutenant colonel

Frank Kendall III

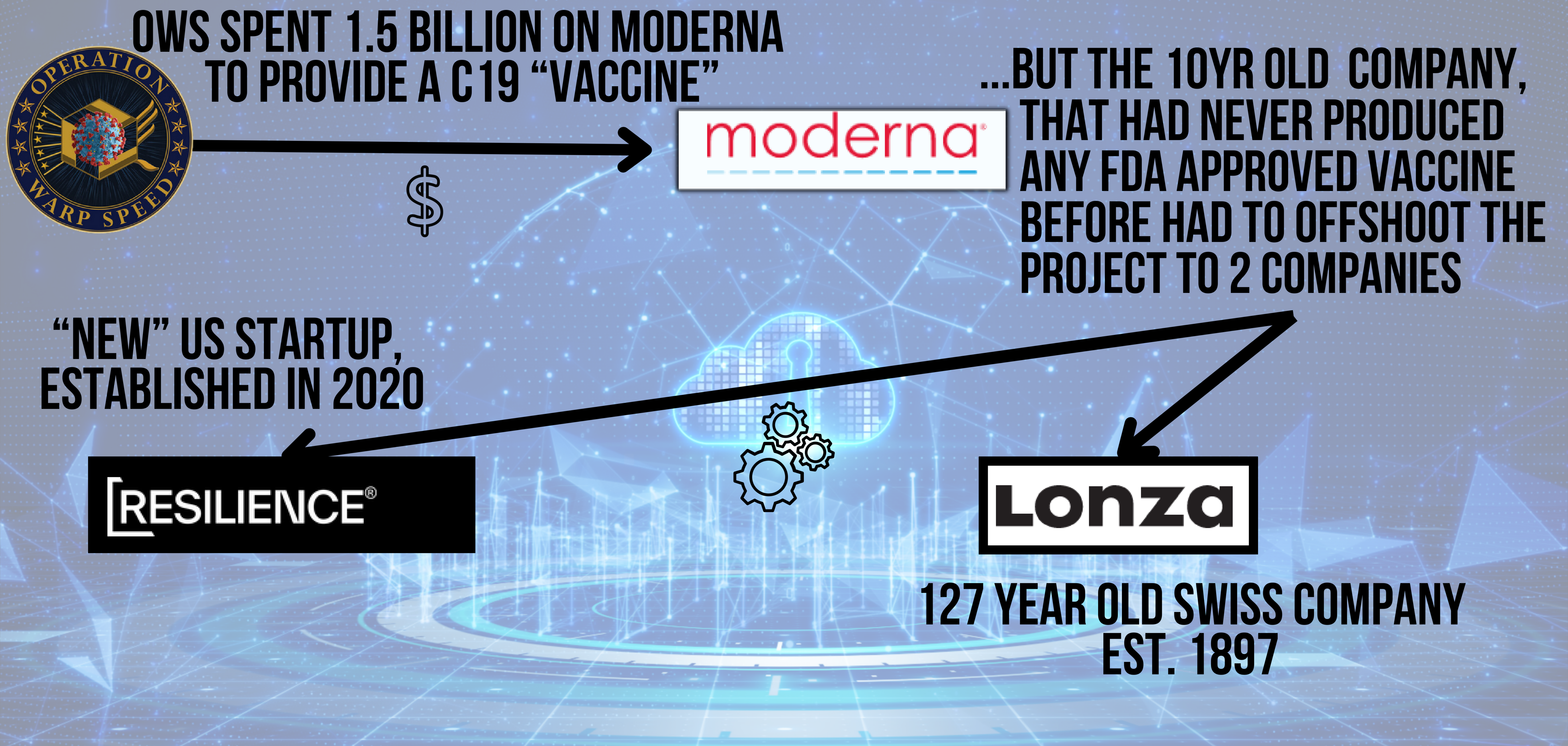


which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]



Biden Administration

On April 27, 2021, President Joe Biden announced Kendall as his nominee to be the 26th Secretary of the Air Force.[23] His Senate confirmation occurred after almost three months of deliberation, due to holds by Senators Mike Lee,[24] Gary Peters[25] and Elizabeth Warren,[26] the latter of whom released her hold after Kendall agreed to extend his post-governmental recusal agreements from two to four years.[26] Kendall was eventually confirmed by voice vote on June 26, 2021,[27][28] administratively sworn in on July 28, 2021[29] and ceremonially sworn in by Secretary of Defense Lloyd Austin on August 4, 2021.[30]



OWS SPENT 1.5 BILLION ON MODERNA TO PROVIDE A C19 “VACCINE”

...BUT THE 10YR OLD COMPANY, THAT HAD NEVER PRODUCED ANY FDA APPROVED VACCINE BEFORE HAD TO OFFSHOOT THE PROJECT TO 2 COMPANIES

“NEW” US STARTUP, ESTABLISHED IN 2020

127 YEAR OLD SWISS COMPANY
EST. 1897

- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. ① ② ③ ④ ⑤

Lonza Group AG was founded in 1897 in Gampel, Switzerland moderna

RESILIENCE

MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN

COUNCIL on FOREIGN RELATIONS

ARCH VENTURE PARTNERS

NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.

FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN. ADDITIONALLY BORIO IS VP OF IN-Q-TEL.

FDA U.S. FOOD & DRUG ADMINISTRATION

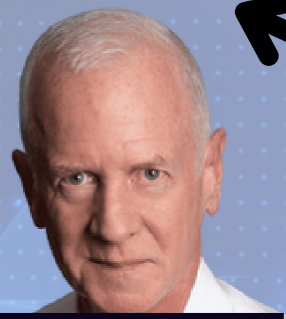
COUNCIL on FOREIGN RELATIONS

ARCH VENTURE PARTNERS

iqt

ALSO ON THE BOARD FOR RESILIENCE IS FORMER FDA COMMISSIONER SCOTT GOTTLIEB AND CHRIS DARBY PRESIDENT OF IN-Q-TEL

FDA U.S. FOOD & DRUG ADMINISTRATION



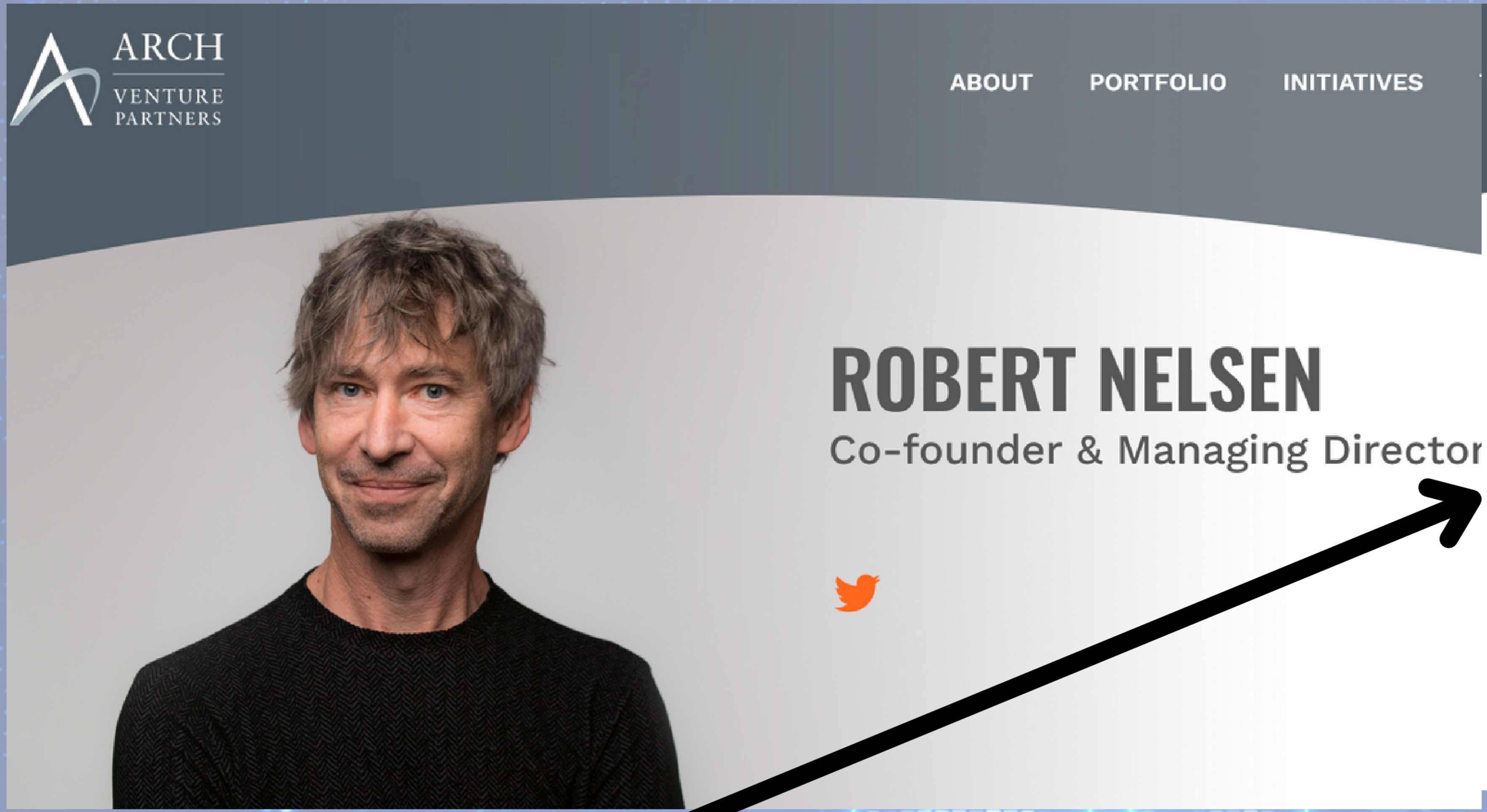
iqt

ALSO ON THE BOARD IS JOE LONSDALE, FOUNDER OF PALANTIR

Palantir

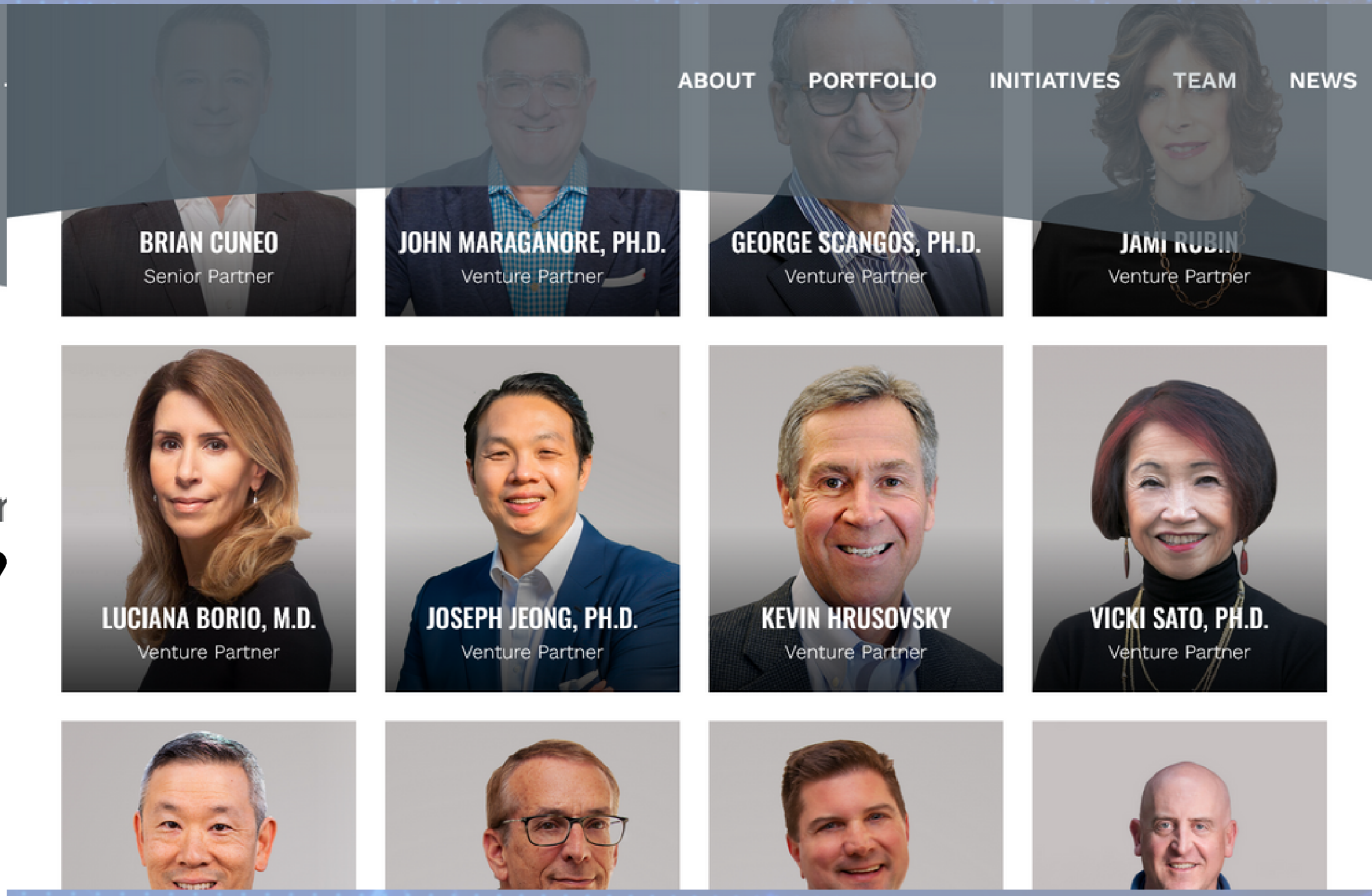
PALANTIR WAS FUNDED BY IN-Q-TEL

PALANTIR CREATED THE TIBERIUS PROGRAM WHICH WAS THE SOFTWARE THAT RAN OWS



ROBERT NELSEN

Co-founder & Managing Director



BRIAN CUNEO
Senior Partner

JOHN MARAGANORE, PH.D.
Venture Partner

GEORGE SCANGOS, PH.D.
Venture Partner

JAMI RUBIN
Venture Partner

LUCIANA BORIO, M.D.
Venture Partner

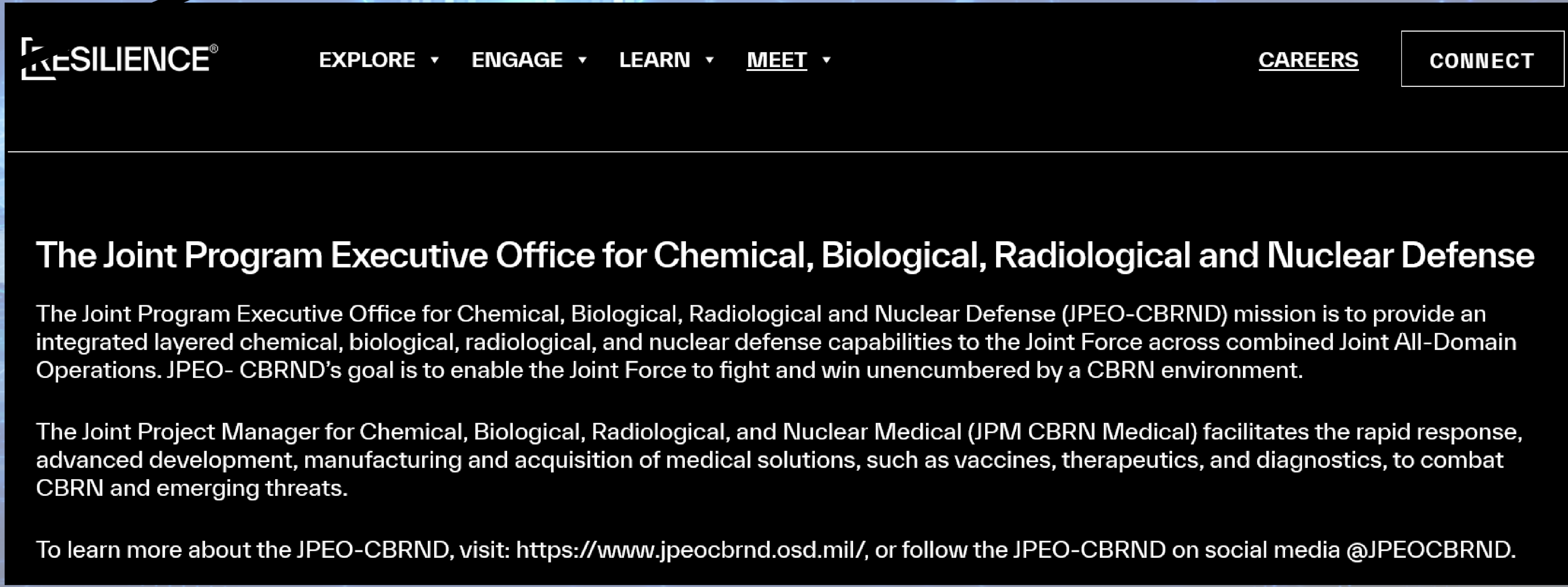
JOSEPH JEONG, PH.D.
Venture Partner

KEVIN HRUSOVSKY
Venture Partner

VICKI SATO, PH.D.
Venture Partner

BORIO ON THE BOARD FOR NELSEN'S COMPANY ARCH

RESILIENCE ADMITS TO WORKING WITH THE DOD VIA THE JPEO-CBRN



The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) mission is to provide an integrated layered chemical, biological, radiological, and nuclear defense capabilities to the Joint Force across combined Joint All-Domain Operations. JPEO- CBRND's goal is to enable the Joint Force to fight and win unencumbered by a CBRN environment.

The Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical) facilitates the rapid response, advanced development, manufacturing and acquisition of medical solutions, such as vaccines, therapeutics, and diagnostics, to combat CBRN and emerging threats.

To learn more about the JPEO-CBRND, visit: https://www.jpeocbrnd.osd.mil/, or follow the JPEO-CBRND on social media @JPEOCBRND.

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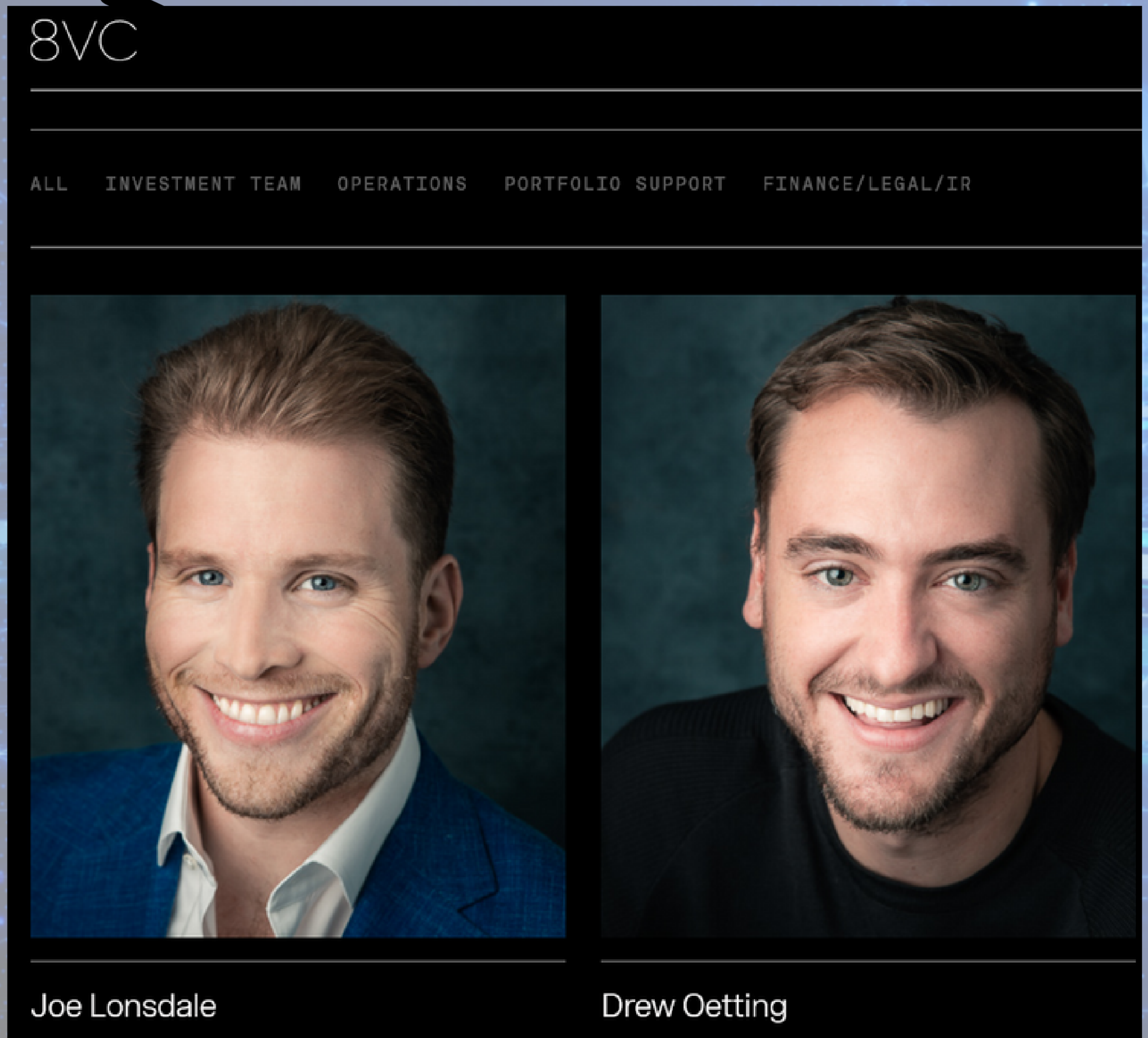
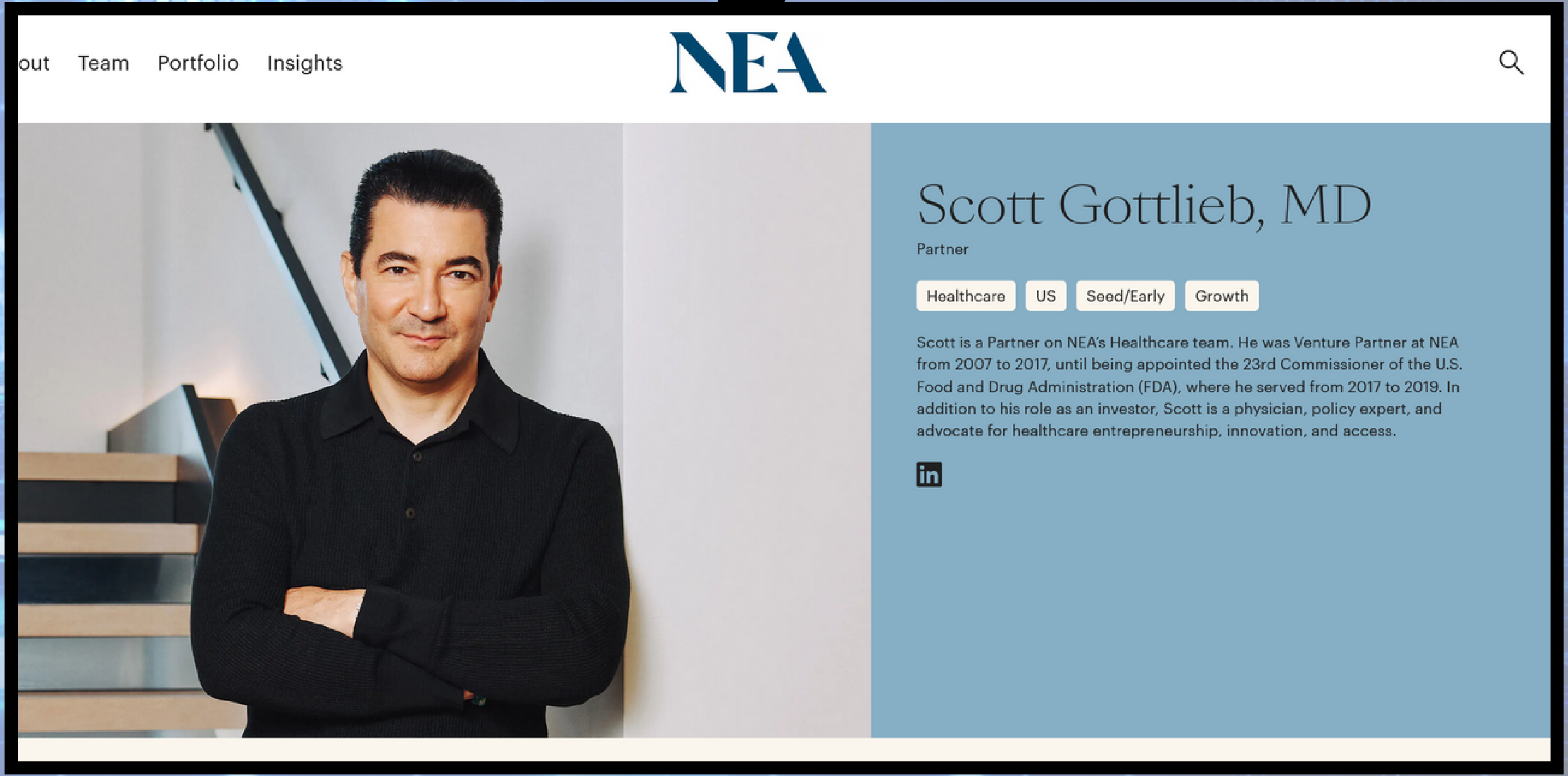


Joe Lonsdale

Drew Oetting



Scott Gottlieb, MD

Partner

Healthcare US Seed/Early Growth

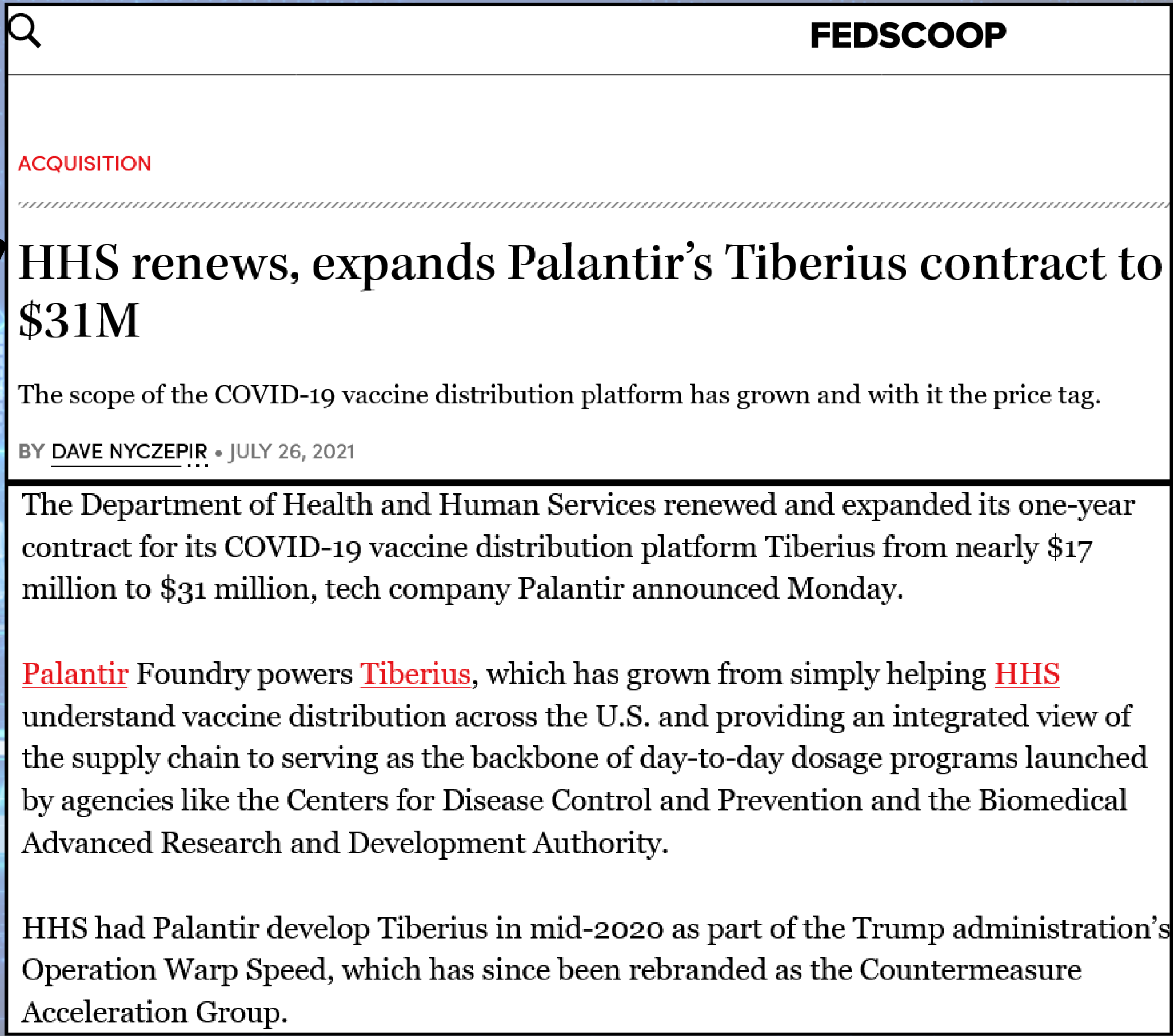
Scott is a Partner on NEA's Healthcare team. He was Venture Partner at NEA from 2007 to 2017, until being appointed the 23rd Commissioner of the U.S. Food and Drug Administration (FDA), where he served from 2017 to 2019. In addition to his role as an investor, Scott is a physician, policy expert, and advocate for healthcare entrepreneurship, innovation, and access.

Joe Lonsdale

Joe Lonsdale founded Palantir.

Palantir created the software for Operation Warp Speed

Palantir



FEDSCOOP

ACQUISITION

HHS renews, expands Palantir's Tiberius contract to $31M

The scope of the COVID-19 vaccine distribution platform has grown and with it the price tag.

BY DAVE NYCZEPIR • JULY 26, 2021

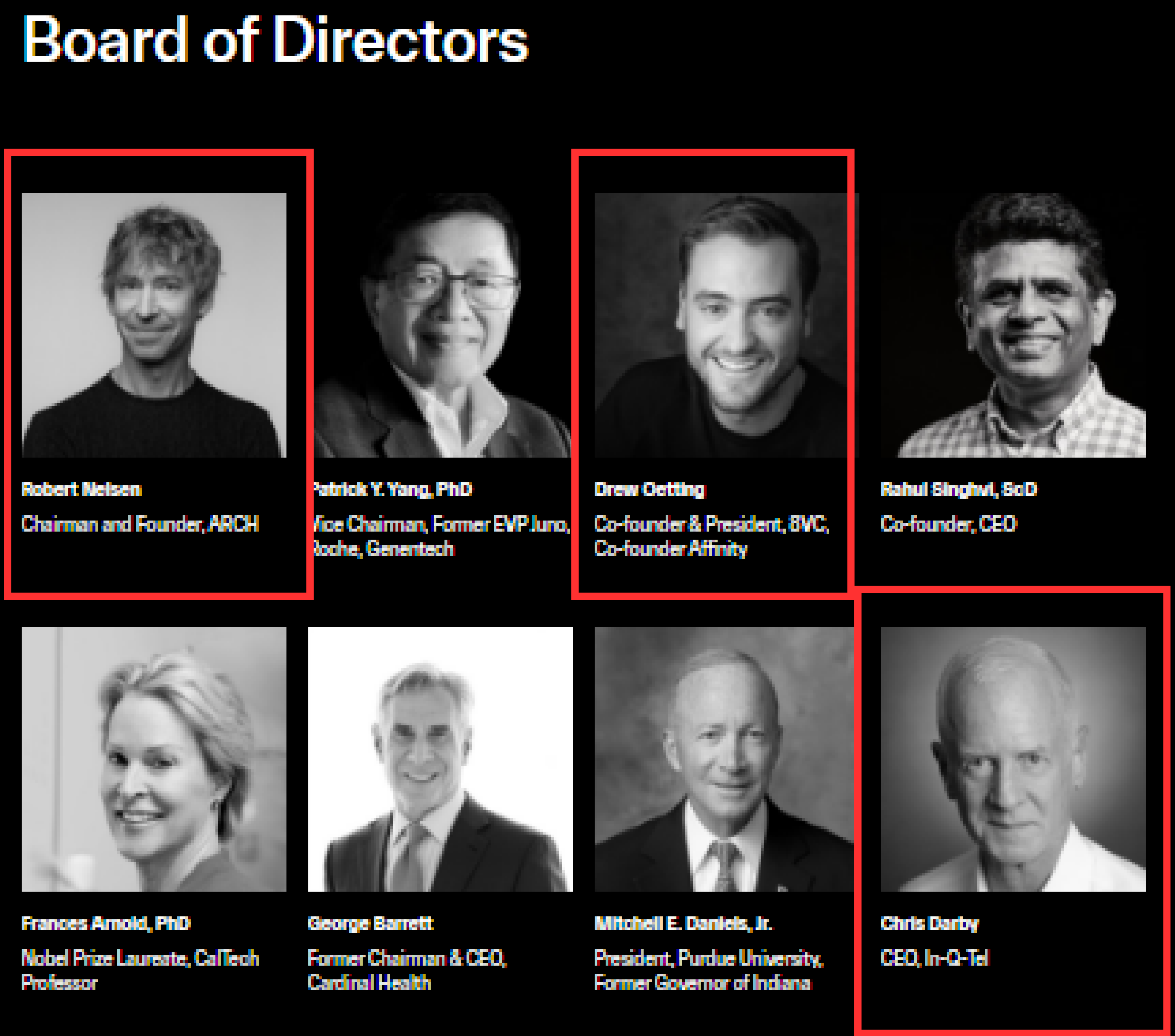
The Department of Health and Human Services renewed and expanded its one-year contract for its COVID-19 vaccine distribution platform Tiberius from nearly $17 million to $31 million, tech company Palantir announced Monday.

Palantir Foundry powers Tiberius, which has grown from simply helping HHS understand vaccine distribution across the U.S. and providing an integrated view of the supply chain to serving as the backbone of day-to-day dosage programs launched by agencies like the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority.

HHS had Palantir develop Tiberius in mid-2020 as part of the Trump administration's Operation Warp Speed, which has since been rebranded as the Countermeasure Acceleration Group.

HTTPS://FEDSCOOP.COM/TAG/TIBERIUS/

RESILIENCE



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Robert Nelsen
Chairman and Founder, ARCH

atrick Y. Yang, PhD
ice Chairman, Former EVP Juno, oche, Genentech

Drew Oetting
Co-founder & President, 8VC, Co-founder Affinity

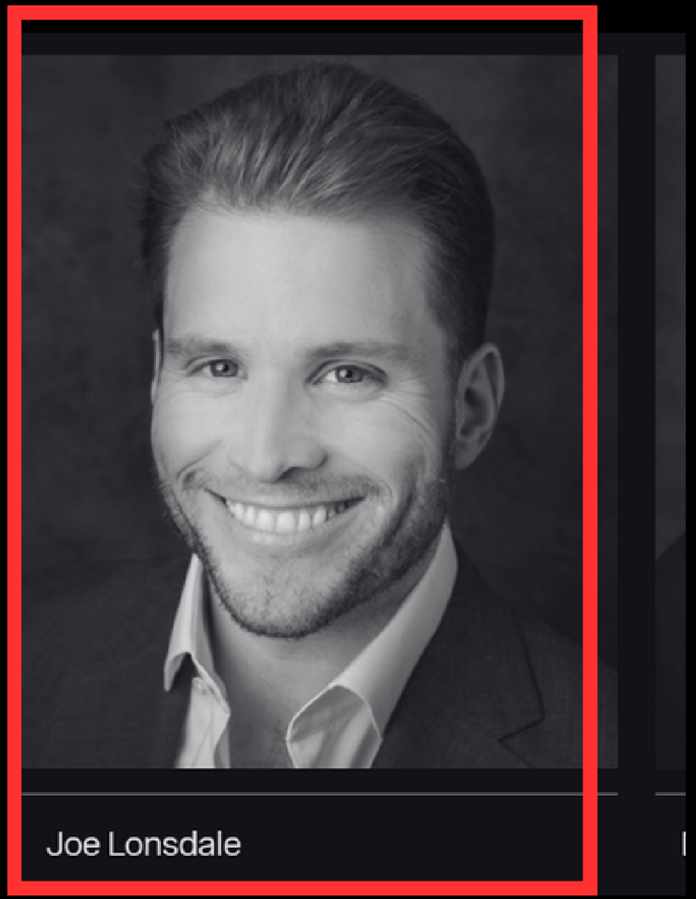
Rahul Singhvi, ScD
Co-founder, CEO

Frances Arnold, PhD
Nobel Prize Laureate, CalTech Professor

George Barrett
Former Chairman & CEO, Cardinal Health

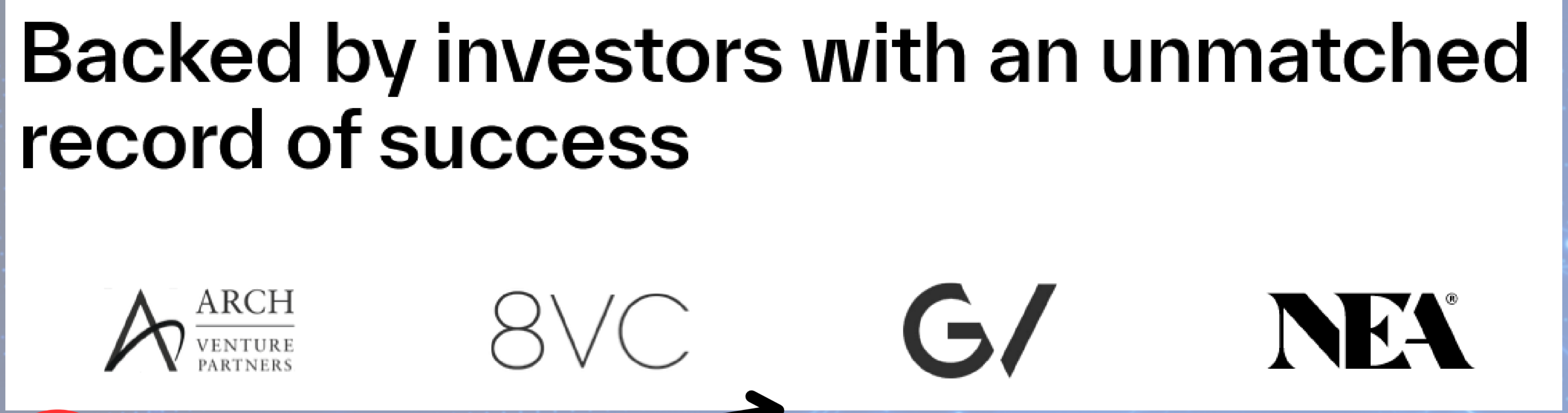
Mitchell E. Daniels, Jr.
President, Purdue University, Former Governor of Indiana

Chris Darby
CEO, In-Q-Tel



Joe Lonsdale

ALL HIGHLIGHTED INDIVIUALS HAVE TIES TO THE INTELLIGENCE COMMUNITY



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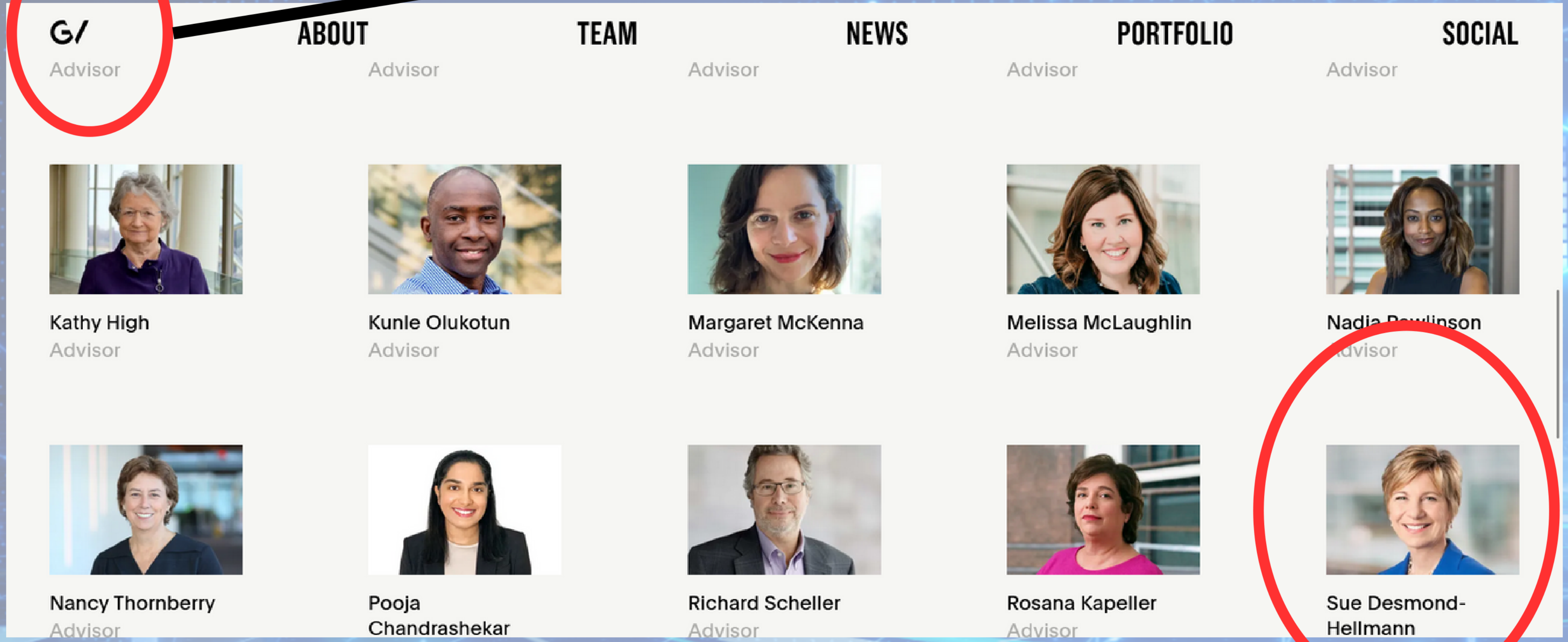
GV = GOOGLE VENTURES
FORMER BILL & MELINDA GATES FOUNDATION CEO AND CURRENT BOARD MEMBER OF: RESILIENCE AND PFIZER,



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Melissa McLaughlin
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Advisor

Nancy Thornberry
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Pooja Chandrashekar

Richard Scheller
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Rosana Kapeller
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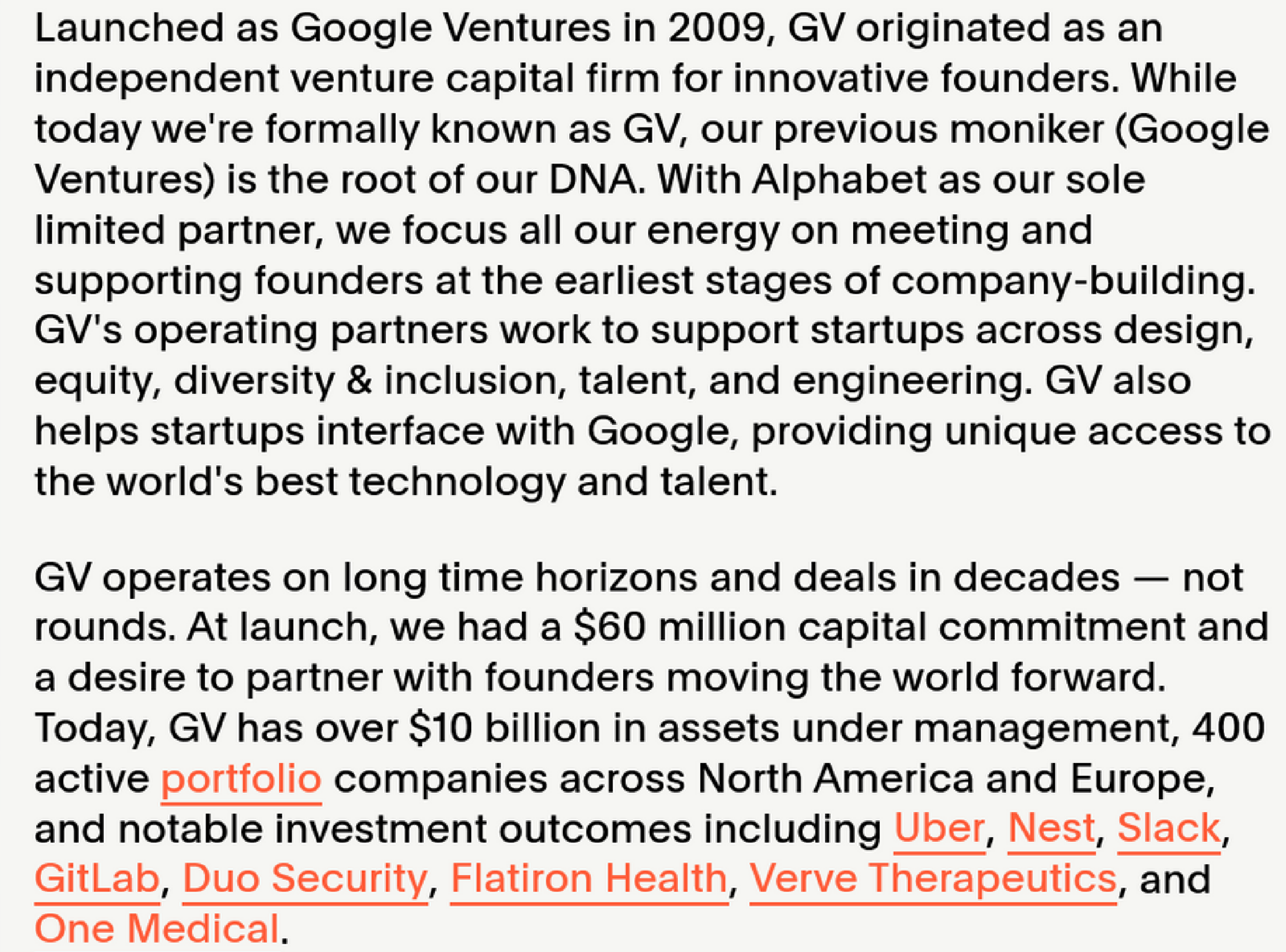
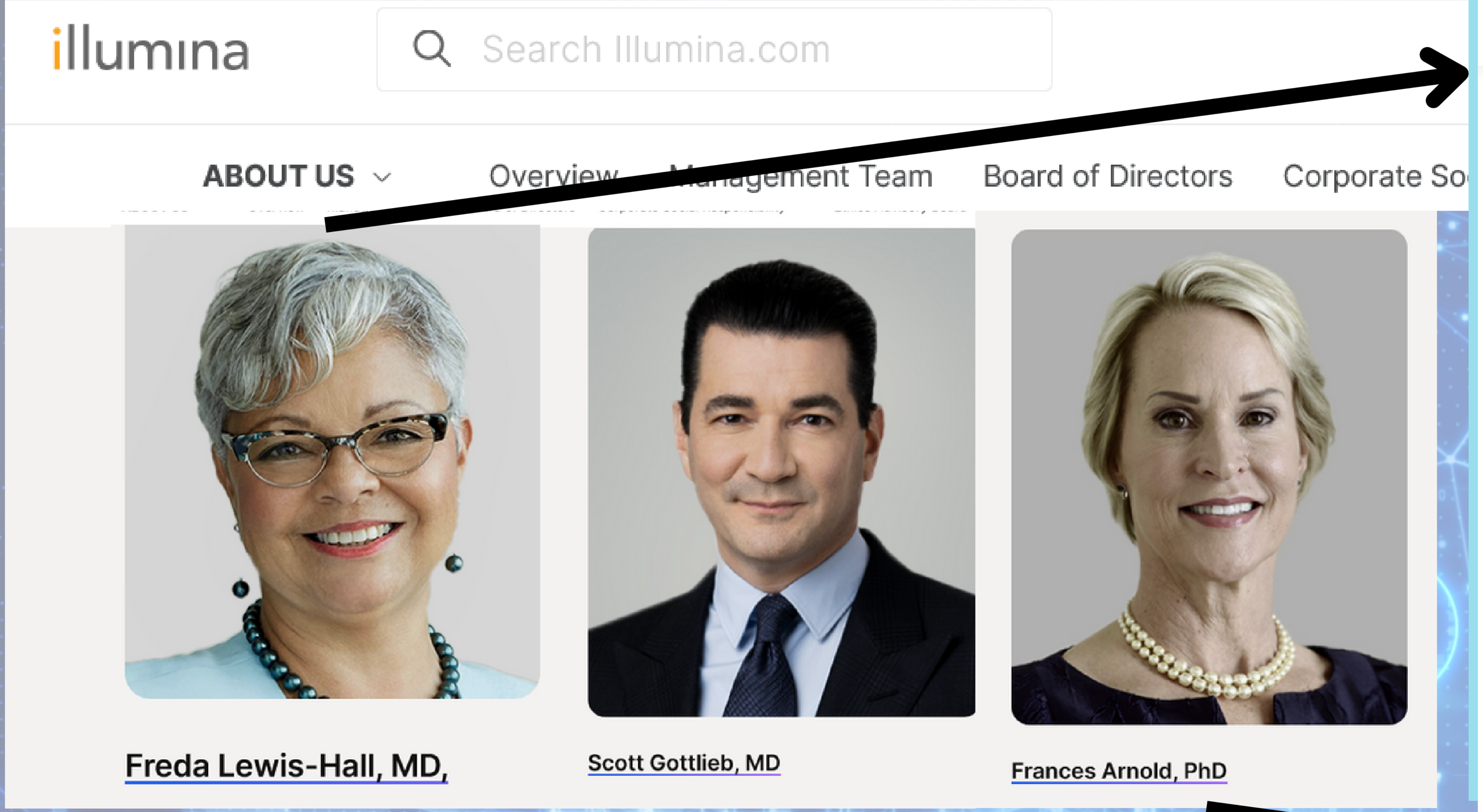
Sue Desmond-Hellmann



Launched as Google Ventures in 2009, GV originated as an independent venture capital firm for innovative founders. While today we're formally known as GV, our previous moniker (Google Ventures) is the root of our DNA. With Alphabet as our sole limited partner, we focus all our energy on meeting and supporting founders at the earliest stages of company-building. GV's operating partners work to support startups across design, equity, diversity & inclusion, talent, and engineering. GV also helps startups interface with Google, providing unique access to the world's best technology and talent.

GV operates on long time horizons and deals in decades — not rounds. At launch, we had a $60 million capital commitment and a desire to partner with founders moving the world forward. Today, GV has over $10 billion in assets under management, 400 active portfolio companies across North America and Europe, and notable investment outcomes including Uber, Nest, Slack, GitLab, Duo Security, Flatiron Health, Verve Therapeutics, and One Medical.

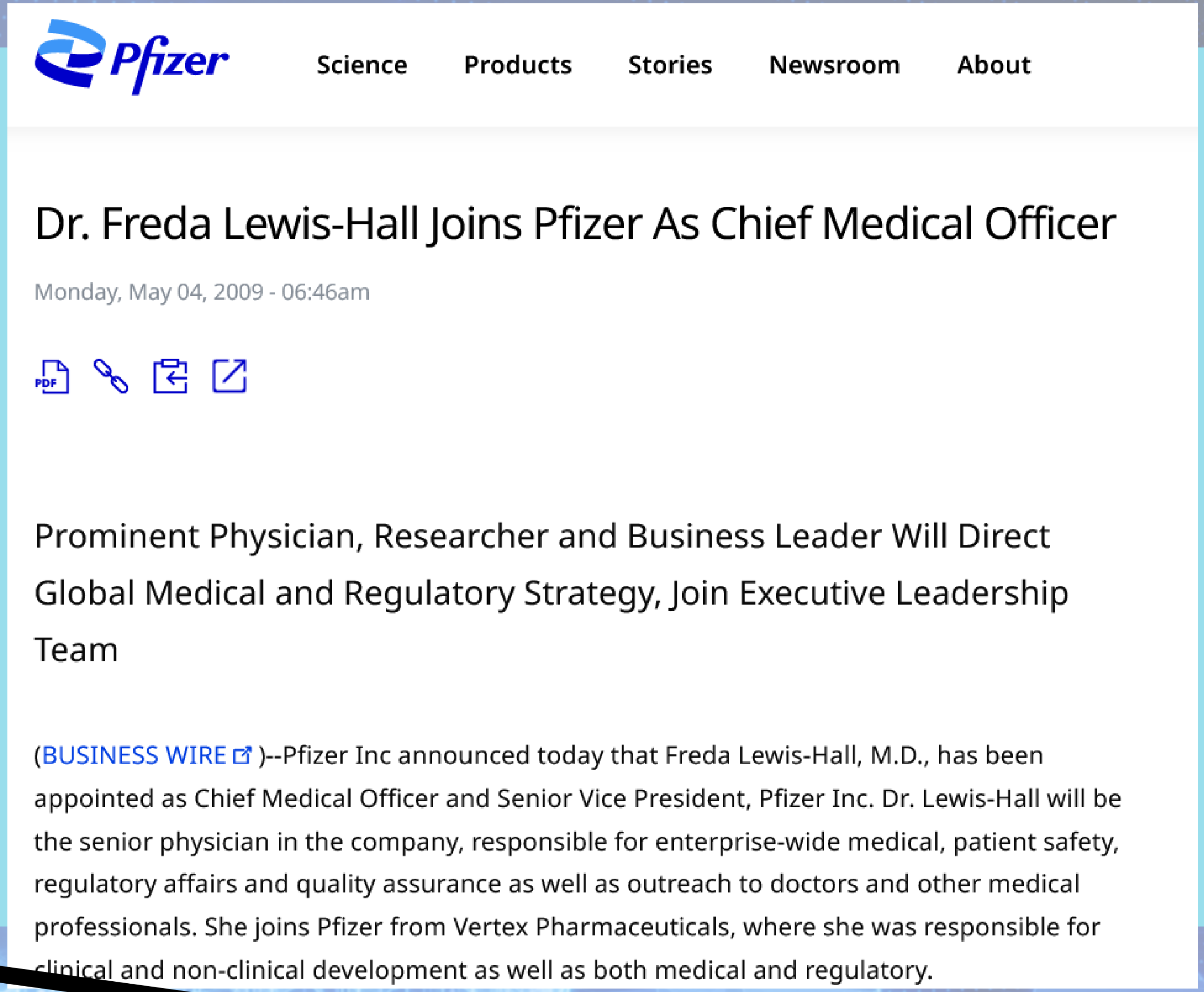
SUSAN DESMOND - HELLMAN



Freda Lewis-Hall, MD,

Scott Gottlieb, MD

Frances Arnold, PhD

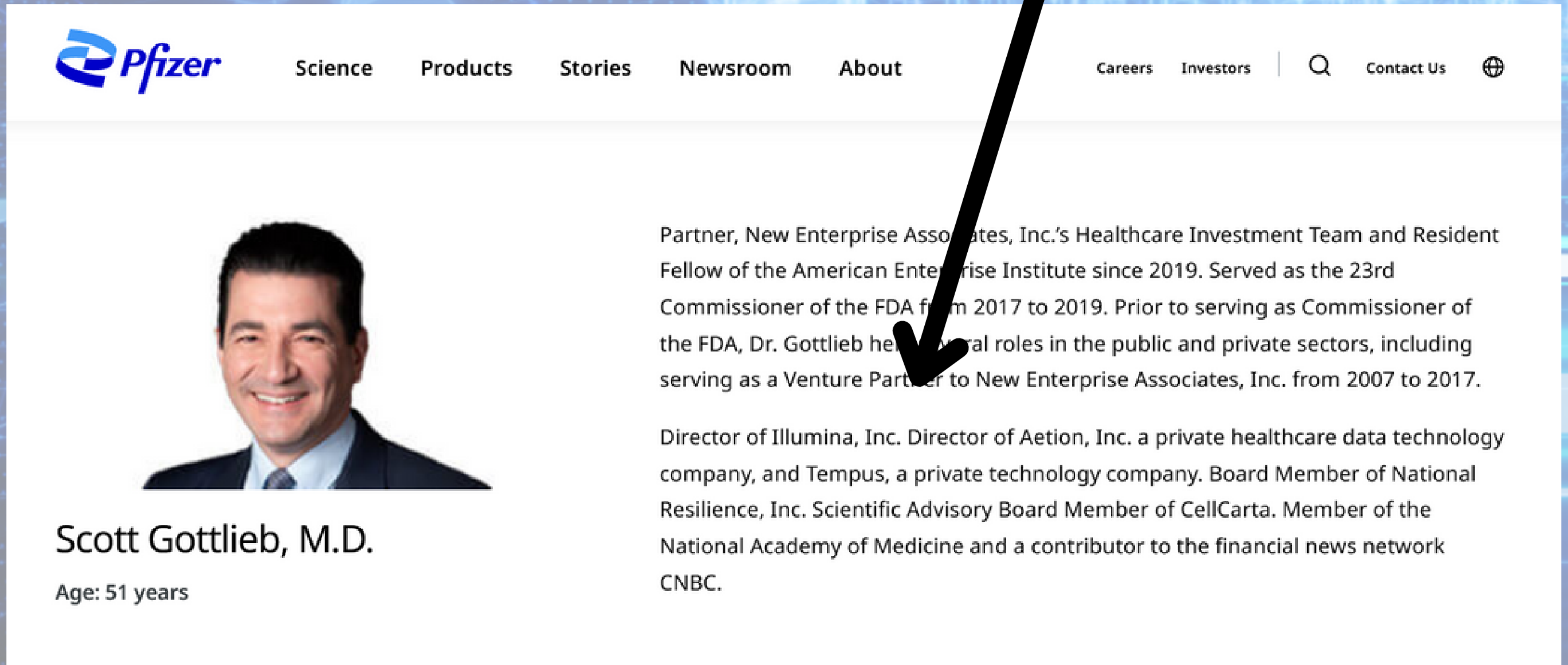


Dr. Freda Lewis-Hall Joins Pfizer As Chief Medical Officer

Monday, May 04, 2009 - 06:46am

Prominent Physician, Researcher and Business Leader Will Direct Global Medical and Regulatory Strategy, Join Executive Leadership Team

(BUSINESS WIRE)--Pfizer Inc announced today that Freda Lewis-Hall, M.D., has been appointed as Chief Medical Officer and Senior Vice President, Pfizer Inc. Dr. Lewis-Hall will be the senior physician in the company, responsible for enterprise-wide medical, patient safety, regulatory affairs and quality assurance as well as outreach to doctors and other medical professionals. She joins Pfizer from Vertex Pharmaceuticals, where she was responsible for clinical and non-clinical development as well as both medical and regulatory.

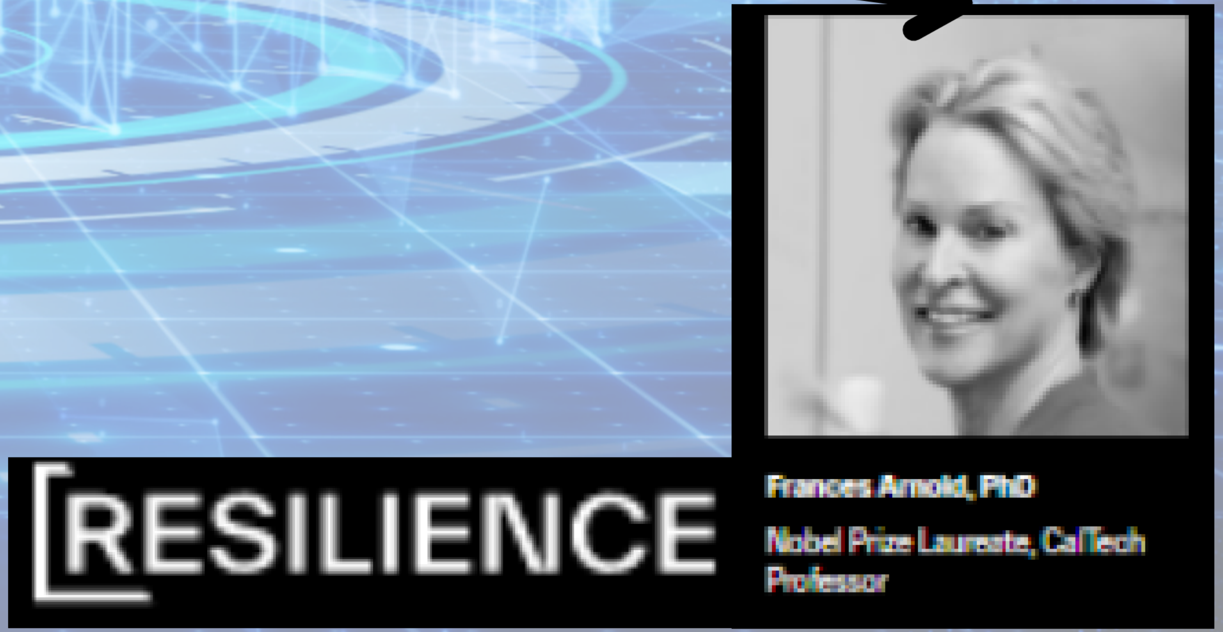


Scott Gottlieb, M.D.

Age: 51 years

Partner, New Enterprise Associates, Inc.'s Healthcare Investment Team and Resident Fellow of the American Enterprise Institute since 2019. Served as the 23rd Commissioner of the FDA from 2017 to 2019. Prior to serving as Commissioner of the FDA, Dr. Gottlieb held several roles in the public and private sectors, including serving as a Venture Partner to New Enterprise Associates, Inc. from 2007 to 2017.

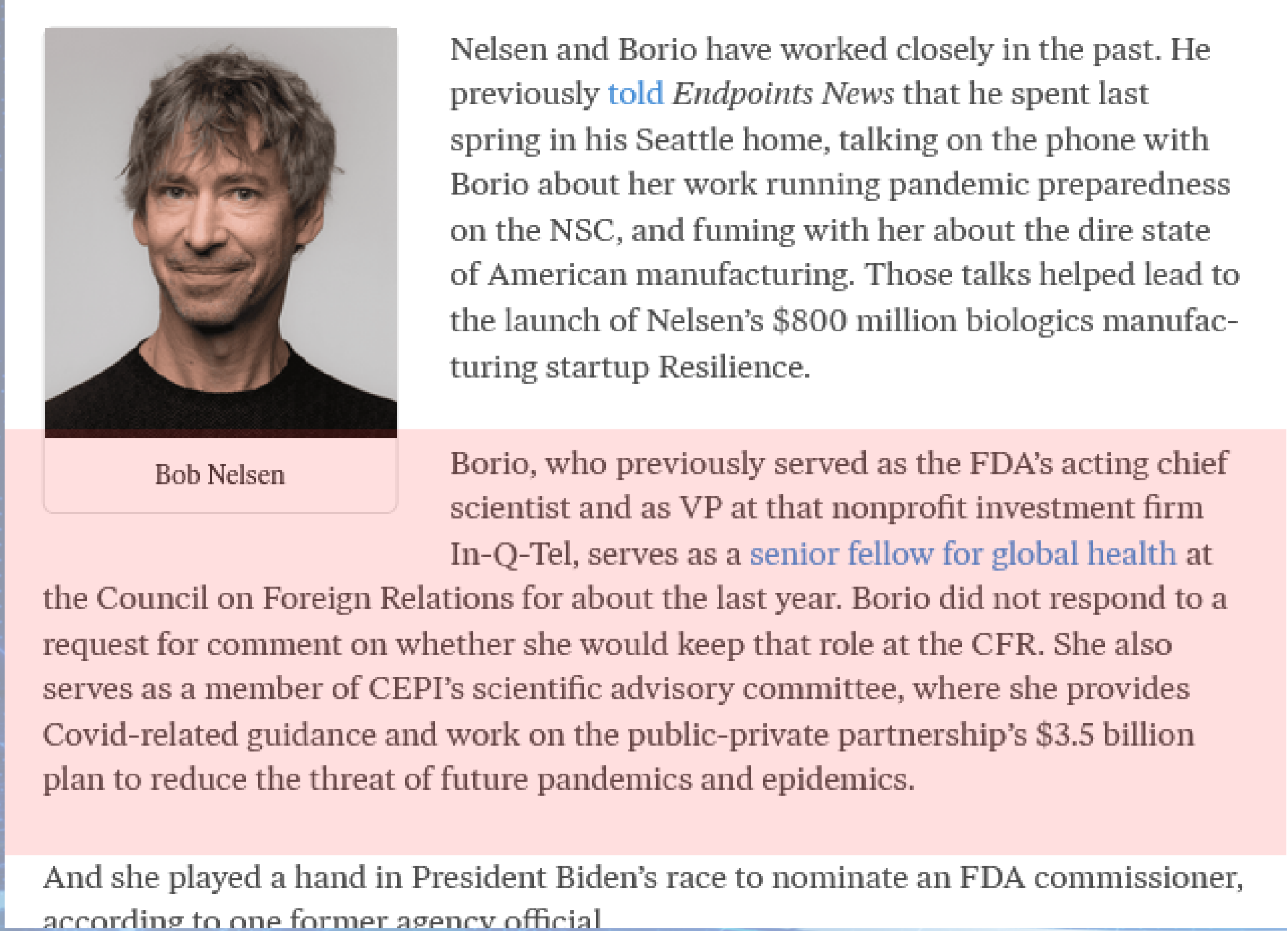
Director of Illumina, Inc. Director of Aetion, Inc. a private healthcare data technology company, and Tempus, a private technology company. Board Member of National Resilience, Inc. Scientific Advisory Board Member of CellCarta. Member of the National Academy of Medicine and a contributor to the financial news network CNBC.



Frances Arnold, PhD

Nobel Prize Laureate, CalTech Professor

ROBERT NELSEN & LUCIANA BORIO



Bob Nelsen

Nelsen and Borio have worked closely in the past. He previously told *Endpoints News* that he spent last spring in his Seattle home, talking on the phone with Borio about her work running pandemic preparedness on the NSC, and fuming with her about the dire state of American manufacturing. Those talks helped lead to the launch of Nelsen's $800 million biologics manufacturing startup Resilience.

Borio, who previously served as the FDA's acting chief scientist and as VP at that nonprofit investment firm In-Q-Tel, serves as a senior fellow for global health at the Council on Foreign Relations for about the last year. Borio did not respond to a request for comment on whether she would keep that role at the CFR. She also serves as a member of CEPI's scientific advisory committee, where she provides Covid-related guidance and work on the public-private partnership's $3.5 billion plan to reduce the threat of future pandemics and epidemics.

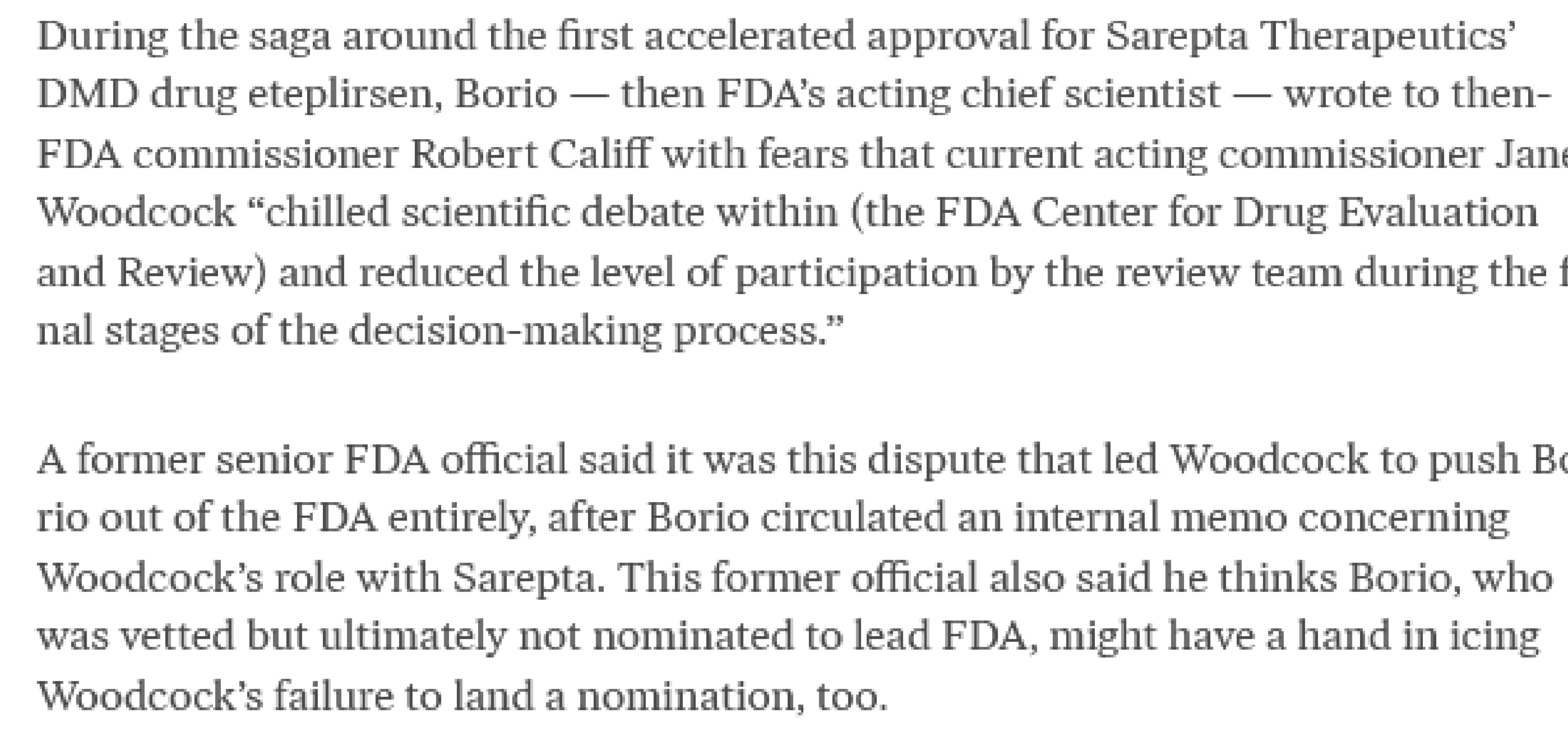
And she played a hand in President Biden's race to nominate an FDA commissioner, according to one former agency official

HTTPS://ARCHIVE.IS/VQK8G

BOTH ON THE COUNCIL FOR FOREIGN RELATIONS

BOTH MEMBERS OF ARCH VENTURES

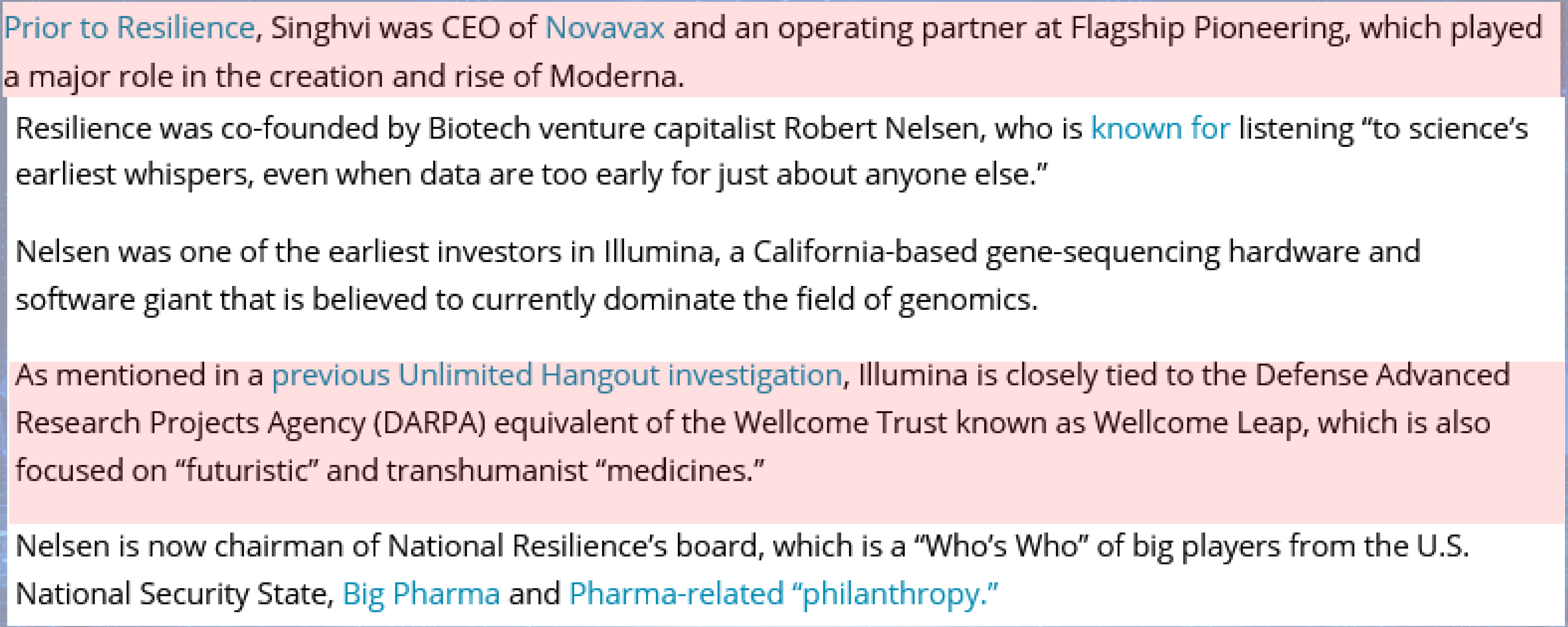
BOTH PLAYED KEY ROLES IN THE "CREATION OF RESILIENCE"



During the saga around the first accelerated approval for Sarepta Therapeutics' DMD drug eteplirsen, Borio — then FDA's acting chief scientist — wrote to then-FDA commissioner Robert Califf with fears that current acting commissioner Jan Woodcock "chilled scientific debate within (the FDA Center for Drug Evaluation and Review) and reduced the level of participation by the review team during the f nal stages of the decision-making process."

A former senior FDA official said it was this dispute that led Woodcock to push Bo rio out of the FDA entirely, after Borio circulated an internal memo concerning Woodcock's role with Sarepta. This former official also said he thinks Borio, who was vetted but ultimately not nominated to lead FDA, might have a hand in icing Woodcock's failure to land a nomination, too.

“SINGHVI WAS ...AND AN OPERATING PARTNER AT FLAGSHIP PIONEERING, WHICH PLAYED A MAJOR ROLE IN THE CREATION OF MODERNA”



Prior to Resilience, Singhvi was CEO of Novavax and an operating partner at Flagship Pioneering, which played a major role in the creation and rise of Moderna.

Resilience was co-founded by Biotech venture capitalist Robert Nelsen, who is known for listening “to science’s earliest whispers, even when data are too early for just about anyone else.”

Nelsen was one of the earliest investors in Illumina, a California-based gene-sequencing hardware and software giant that is believed to currently dominate the field of genomics.

As mentioned in a previous Unlimited Hangout investigation, Illumina is closely tied to the Defense Advanced Research Projects Agency (DARPA) equivalent of the Wellcome Trust known as Wellcome Leap, which is also focused on “futuristic” and transhumanist “medicines.”

Nelsen is now chairman of National Resilience’s board, which is a “Who’s Who” of big players from the U.S. National Security State, Big Pharma and Pharma-related “philanthropy.”

HTTPS://CHILDRENSHEALTHDEFENSE.ORG/DEFENDER/CIA-LINKED-MRNA-MODERNA-OMICRON-COVID-BOOSTER-SHOT/

CHILDREN’S HEALTH DEFENSE ET.
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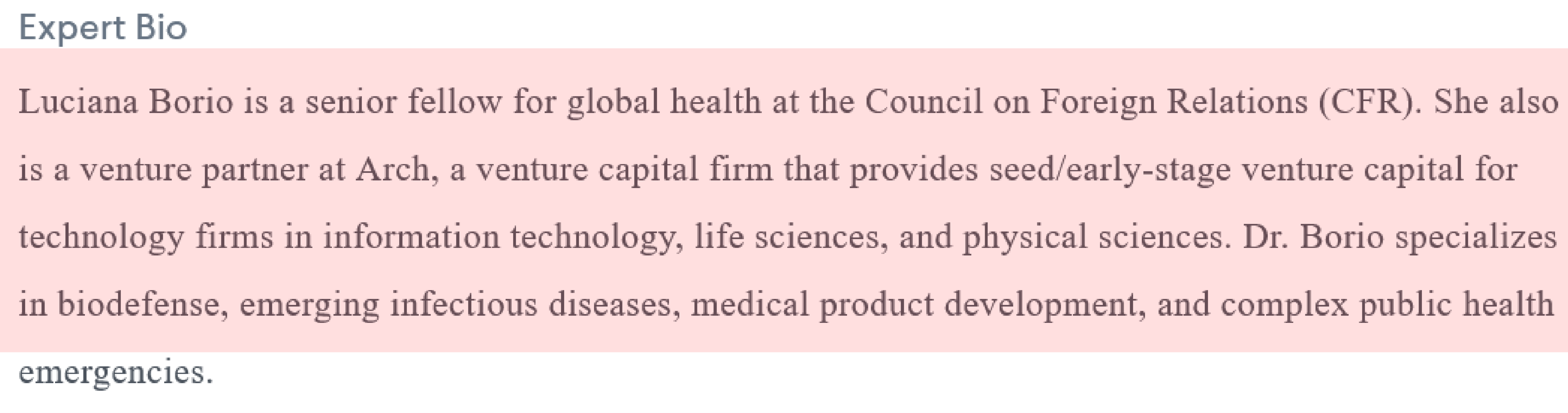
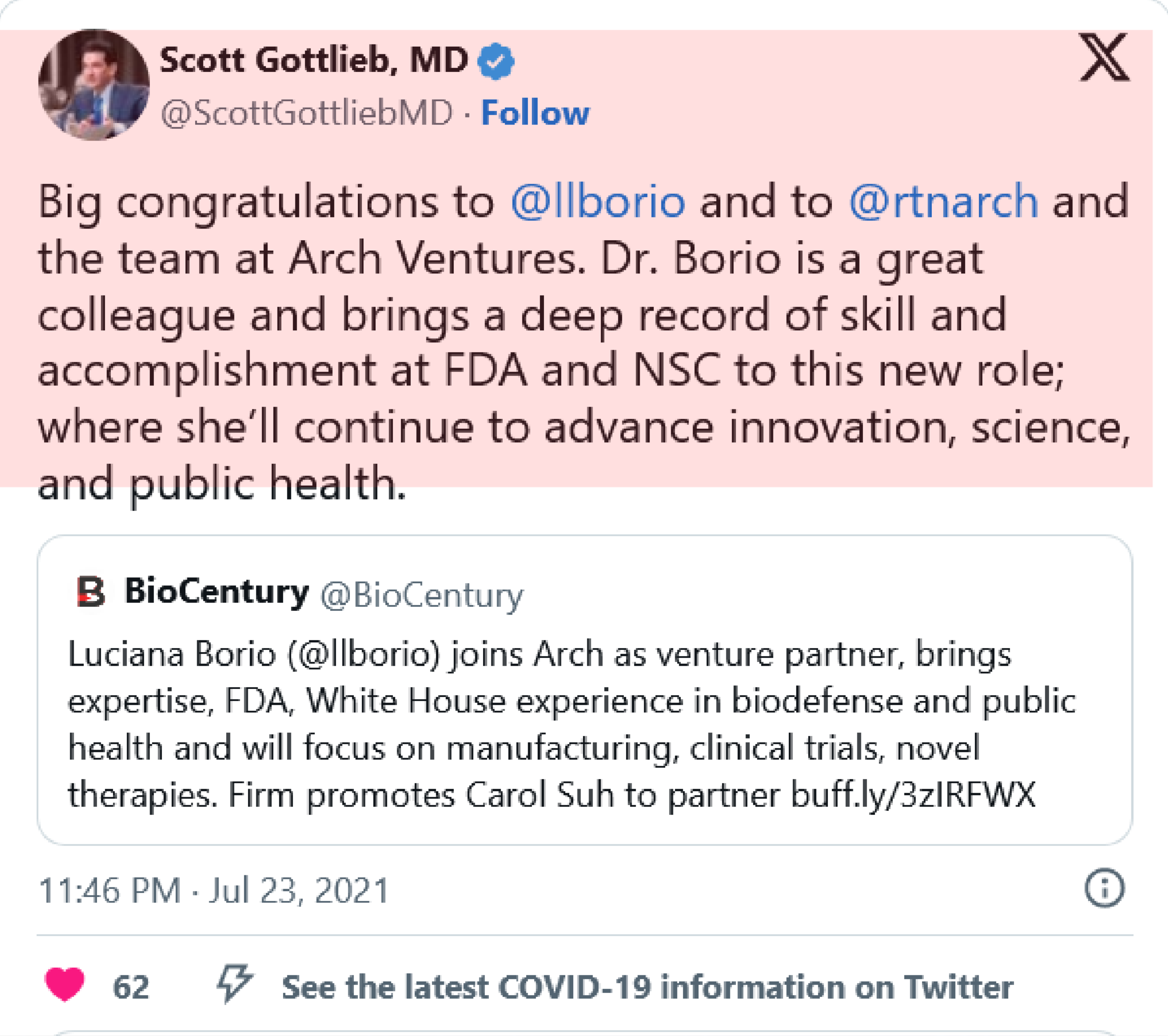
LUCIANA BORIO



Expert Bio

Luciana Borio is a senior fellow for global health at the Council on Foreign Relations (CFR). She also is a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies.

GOTTLIEB



Scott Gottlieb, MD @ScottGottliebMD · Follow

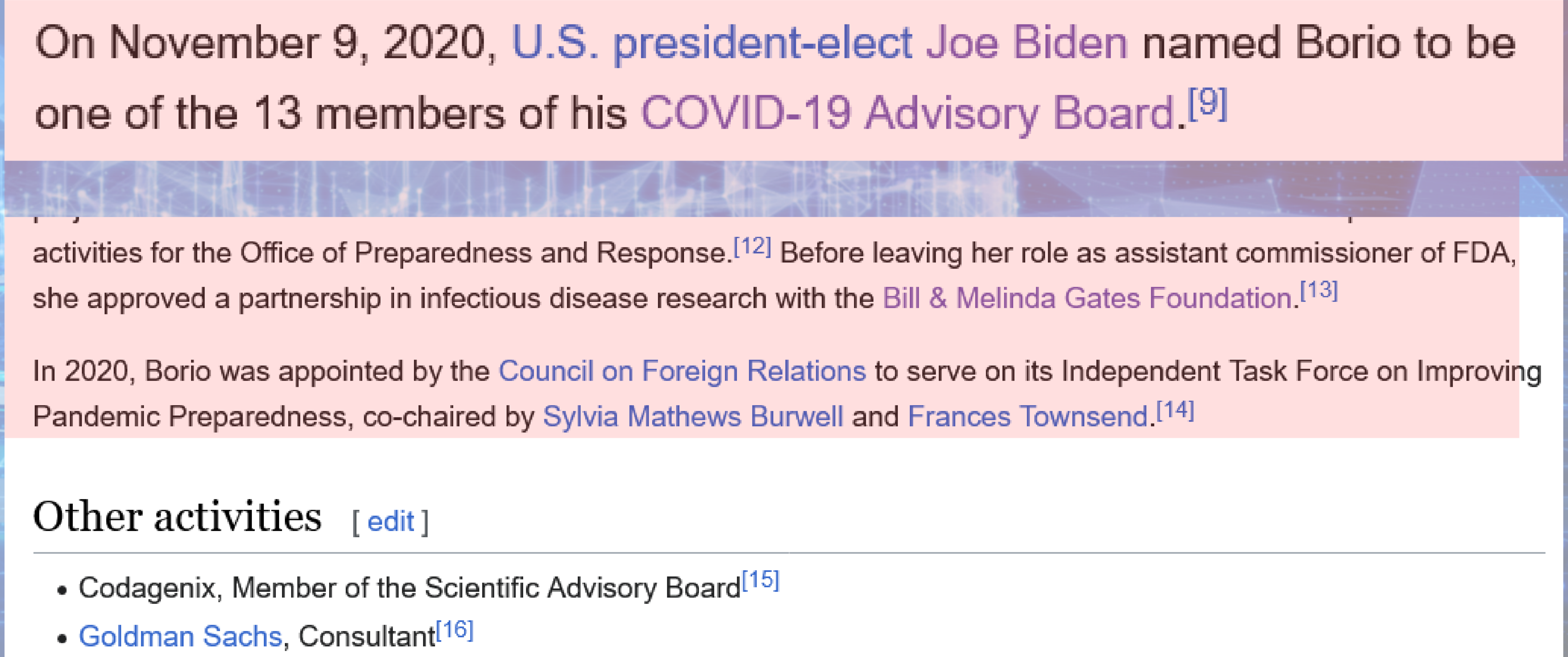
Big congratulations to @llborio and to @rtnarch and the team at Arch Ventures. Dr. Borio is a great colleague and brings a deep record of skill and accomplishment at FDA and NSC to this new role; where she'll continue to advance innovation, science, and public health.

BioCentury @BioCentury

Luciana Borio (@llborio) joins Arch as venture partner, brings expertise, FDA, White House experience in biodefense and public health and will focus on manufacturing, clinical trials, novel therapies. Firm promotes Carol Suh to partner buff.ly/3zIRFWX

11:46 PM · Jul 23, 2021

62 See the latest COVID-19 information on Twitter



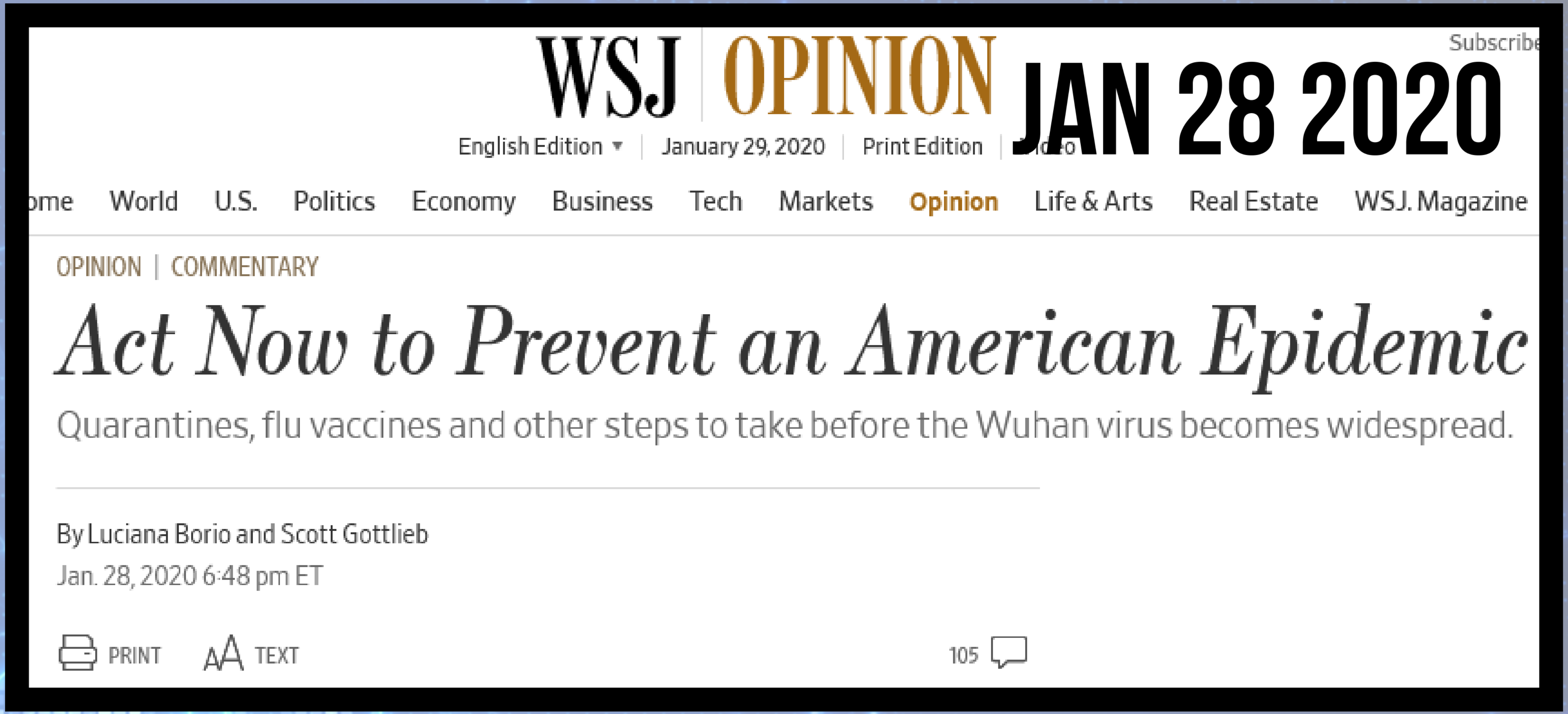
On November 9, 2020, U.S. president-elect Joe Biden named Borio to be one of the 13 members of his COVID-19 Advisory Board.[9]

activities for the Office of Preparedness and Response.[12] Before leaving her role as assistant commissioner of FDA, she approved a partnership in infectious disease research with the Bill & Melinda Gates Foundation.[13]

In 2020, Borio was appointed by the Council on Foreign Relations to serve on its Independent Task Force on Improving Pandemic Preparedness, co-chaired by Sylvia Mathews Burwell and Frances Townsend.[14]

Other activities [edit]

- Codagenix, Member of the Scientific Advisory Board[15]
- Goldman Sachs, Consultant[16]



JAN 28 2020

OPINION | COMMENTARY

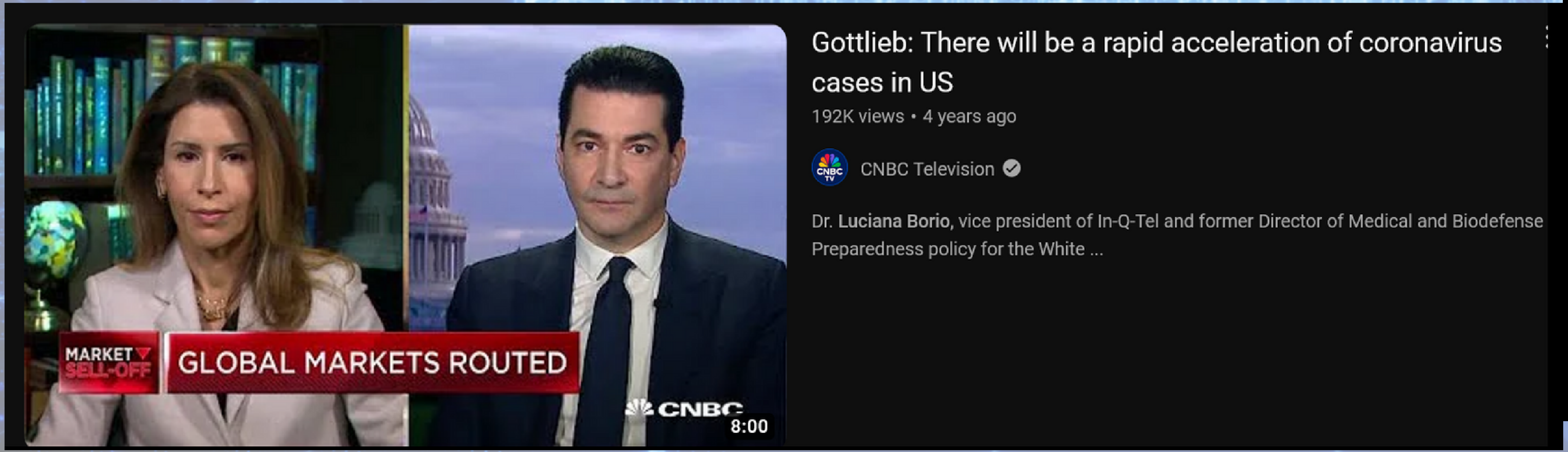
Act Now to Prevent an American Epidemic

Quarantines, flu vaccines and other steps to take before the Wuhan virus becomes widespread.

By Luciana Borio and Scott Gottlieb

Jan. 28, 2020 6:48 pm ET

GOTTLIEB & LUCIANA BORIO

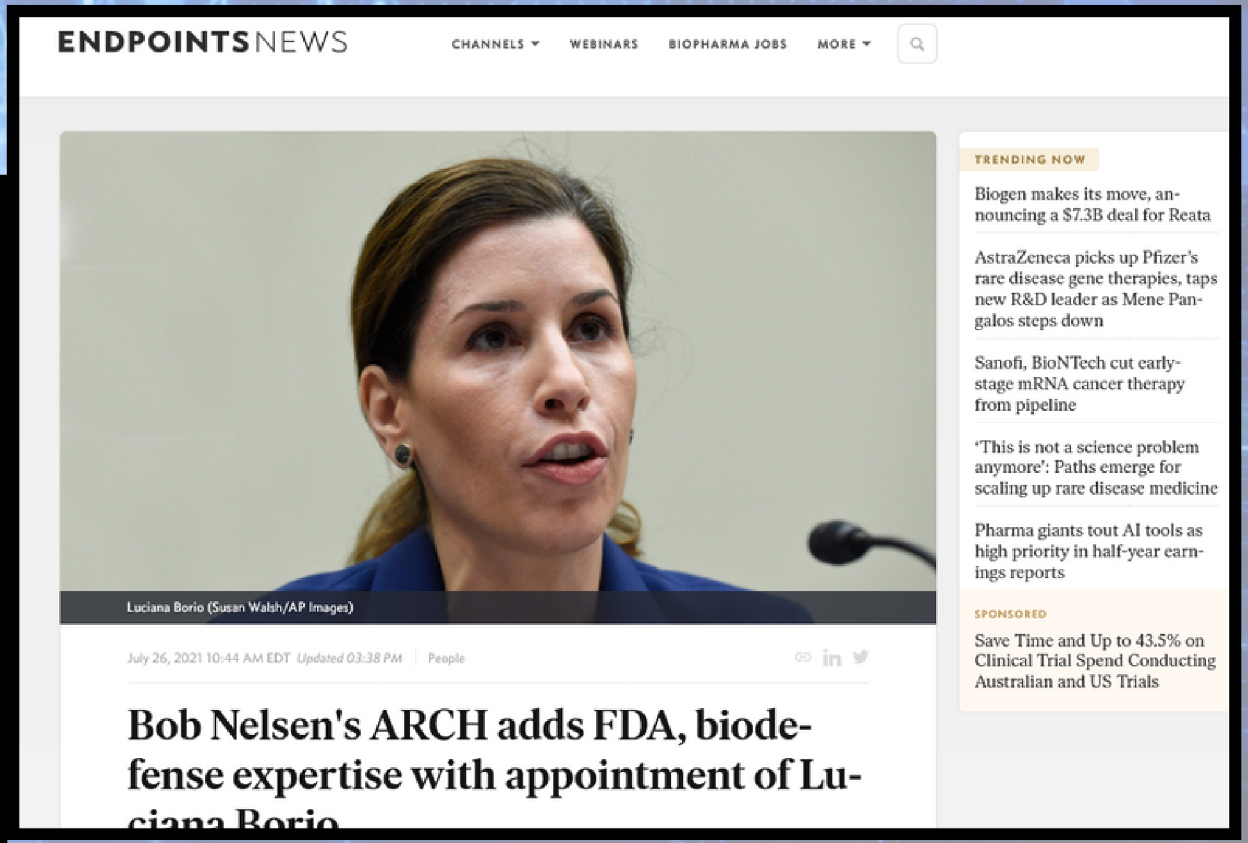


Gottlieb: There will be a rapid acceleration of coronavirus cases in US

192K views • 4 years ago

CNBC Television

Dr. **Luciana Borio**, vice president of In-Q-Tel and former Director of Medical and Biodefense Preparedness policy for the White ...



Luciana Borio (Susan Walsh/AP Images)

July 26, 2021 10:44 AM EDT *Updated 03:38 PM* | People

Bob Nelsen's ARCH adds FDA, biodefense expertise with appointment of Luciana Borio

TRENDING NOW

Biogen makes its move, announcing a $7.3B deal for Reata

AstraZeneca picks up Pfizer's rare disease gene therapies, taps new R&D leader as Mene Pangalos steps down

Sanofi, BioNTech cut early-stage mRNA cancer therapy from pipeline

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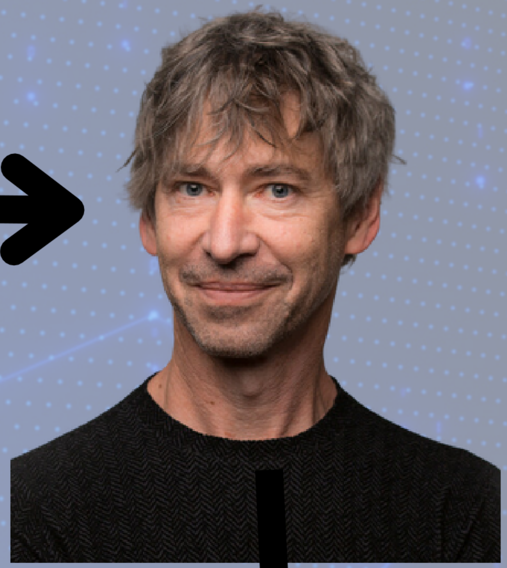
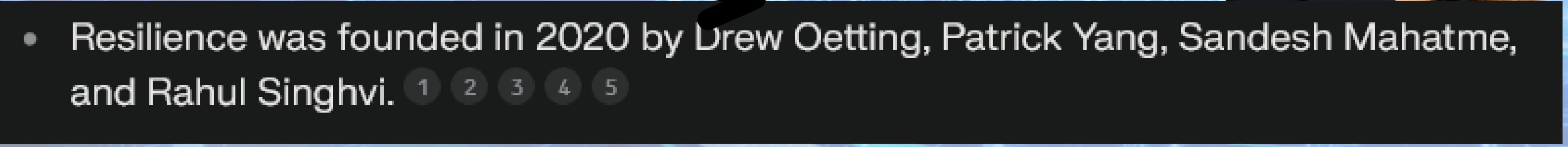


MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN

WHO MADE ROBERT NELSEN THE HEAD OF THE BOARD OF DIRECTORS

NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.



- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. 1 2 3 4 5

BORIO IS ALSO A JOHNS HOPKINS GRAD, FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN

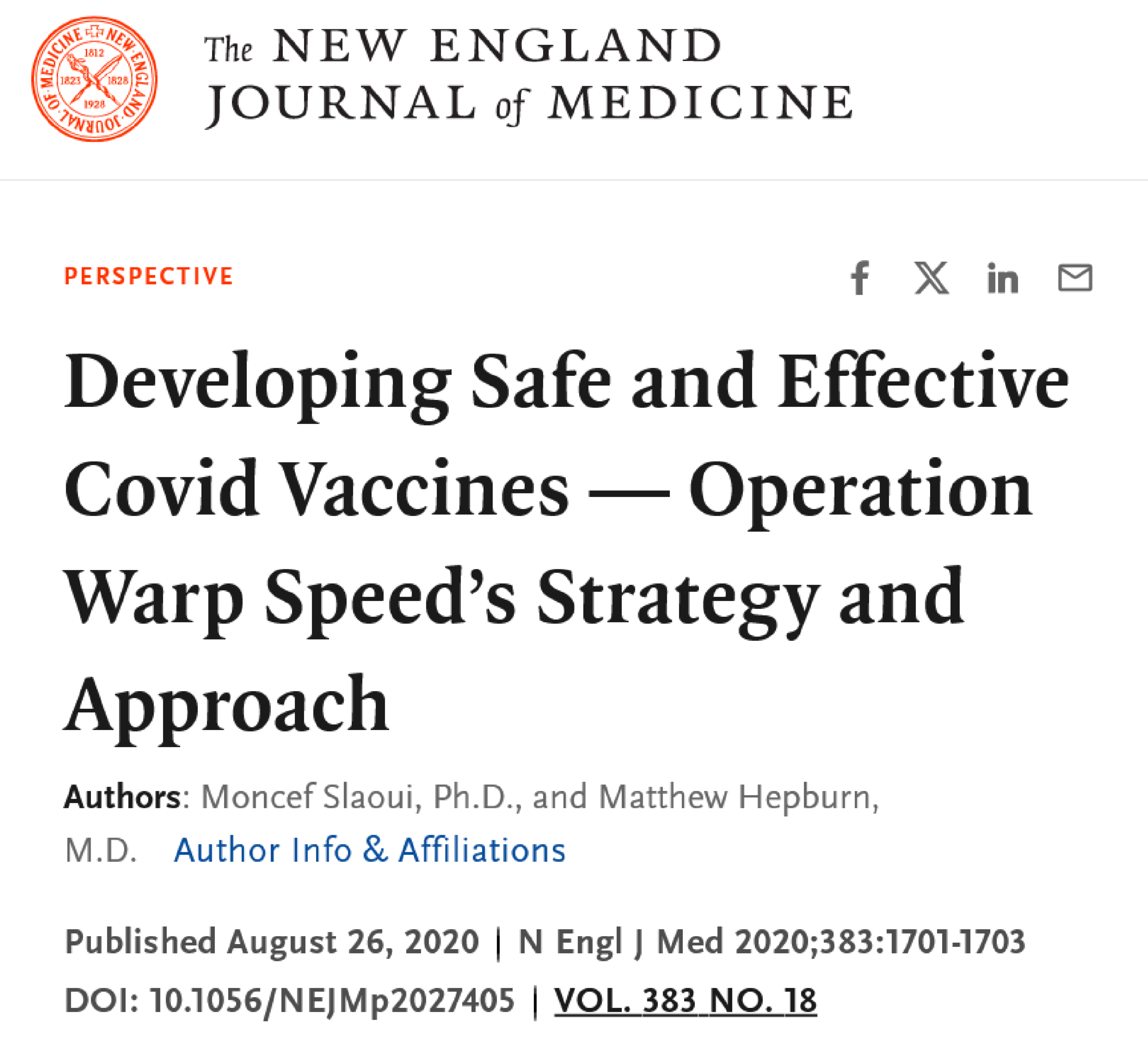
Palantir

OPERATION WARP SPEED

HEADS OF OWS:

MONCEF SLAOUI

MATTHEW HEPBURN [DARPA]



The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach

Authors: Moncef Slaoui, Ph.D., and Matthew Hepburn, M.D. Author Info & Affiliations

Published August 26, 2020 | N Engl J Med 2020;383:1701-1703

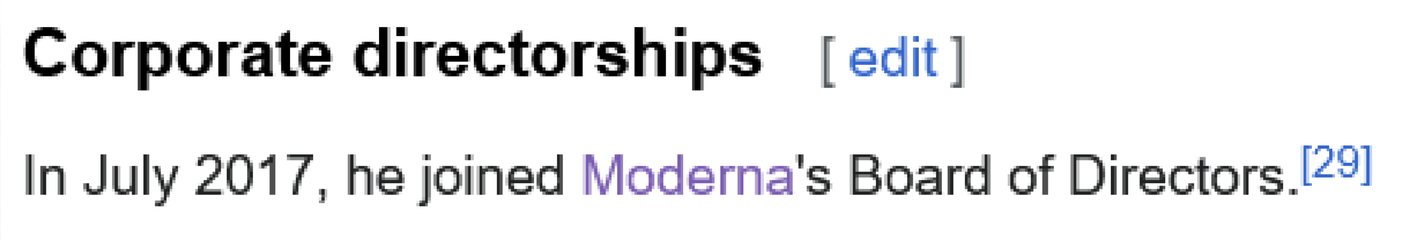
DOI: 10.1056/NEJMp2027405 | VOL. 383 NO. 18

HEPBURN LEAD THE ADEPT PROGRAM

SLAOUI WAS ON THE BOARD FOR GSK, & JOINED MODERNA'S BOARD OF DIRECTORS IN 2017

Moncef Slaoui

Slaoui with GlaxoSmithKline CEO Emma Walmsley (December 2016)

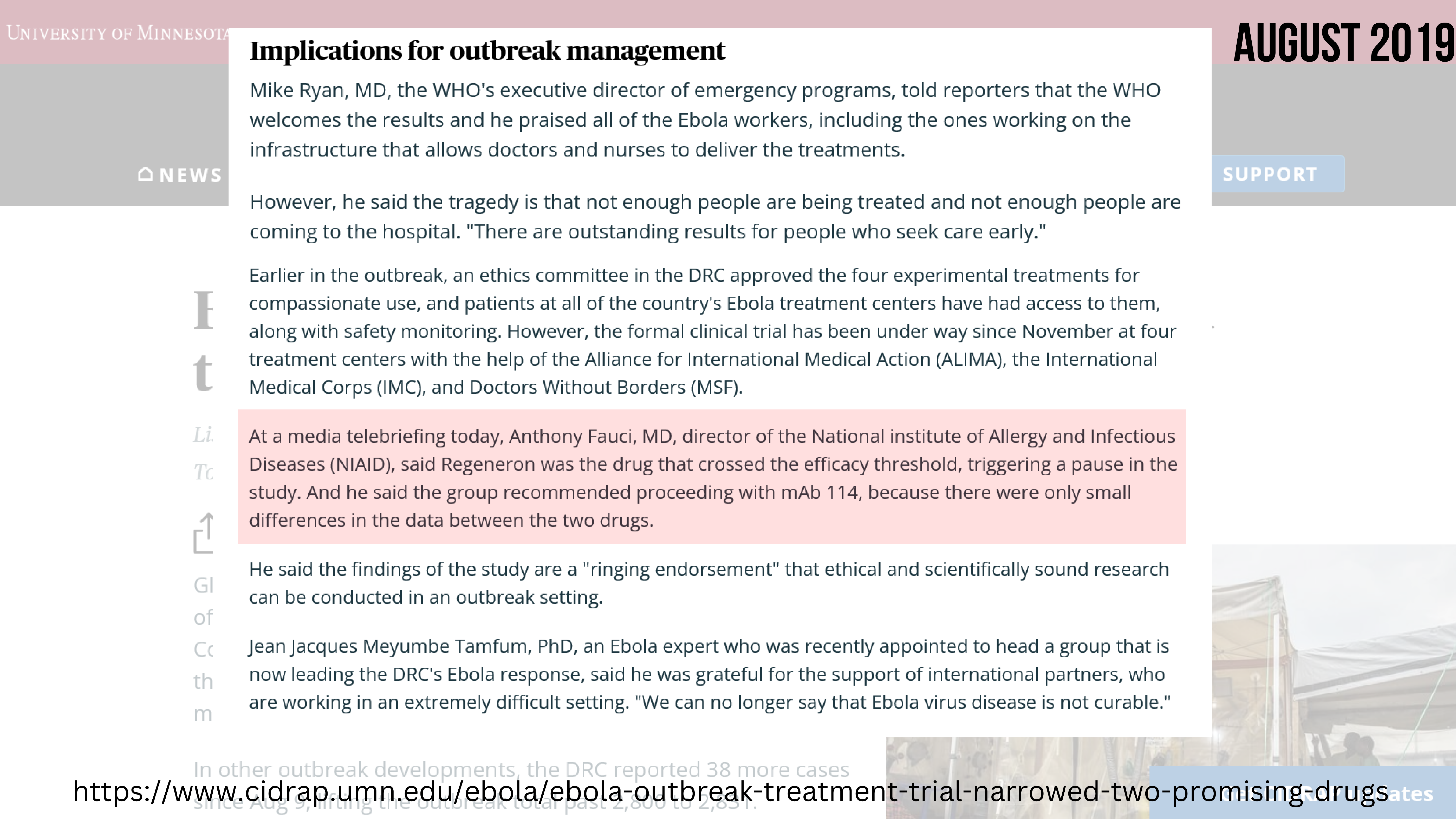


Corporate directorships [edit]

In July 2017, he joined Moderna's Board of Directors.[29]

HTTPS://WWW.NEJM.ORG/DOI/10.1056/NEJMP2027405

AUGUST 2019



Implications for outbreak management

Mike Ryan, MD, the WHO's executive director of emergency programs, told reporters that the WHO welcomes the results and he praised all of the Ebola workers, including the ones working on the infrastructure that allows doctors and nurses to deliver the treatments.

However, he said the tragedy is that not enough people are being treated and not enough people are coming to the hospital. "There are outstanding results for people who seek care early."

Earlier in the outbreak, an ethics committee in the DRC approved the four experimental treatments for compassionate use, and patients at all of the country's Ebola treatment centers have had access to them, along with safety monitoring. However, the formal clinical trial has been under way since November at four treatment centers with the help of the Alliance for International Medical Action (ALIMA), the International Medical Corps (IMC), and Doctors Without Borders (MSF).

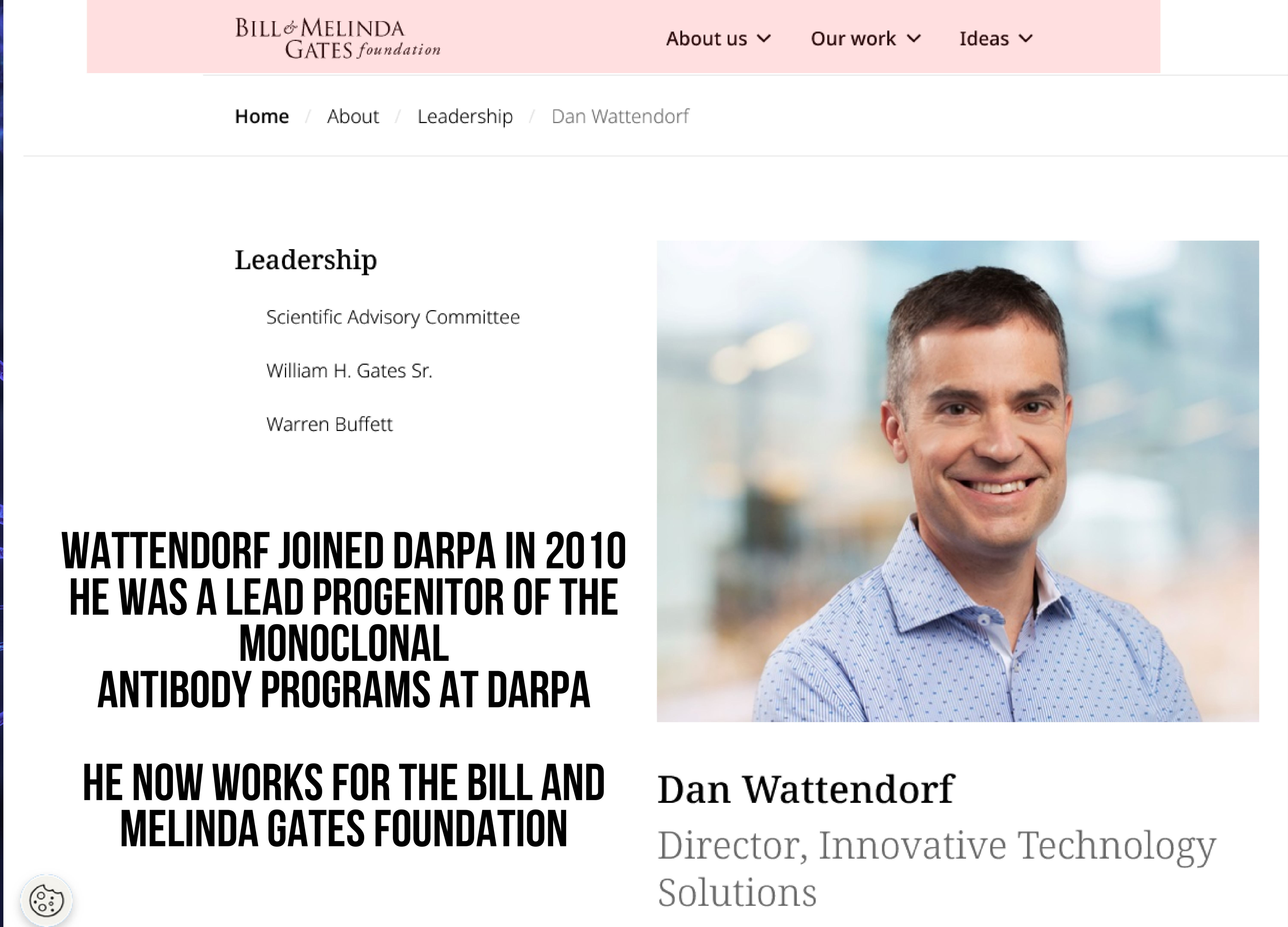
At a media telebriefing today, Anthony Fauci, MD, director of the National institute of Allergy and Infectious Diseases (NIAID), said Regeneron was the drug that crossed the efficacy threshold, triggering a pause in the study. And he said the group recommended proceeding with mAb 114, because there were only small differences in the data between the two drugs.

He said the findings of the study are a "ringing endorsement" that ethical and scientifically sound research can be conducted in an outbreak setting.

Jean Jacques Meyumbe Tamfum, PhD, an Ebola expert who was recently appointed to head a group that is now leading the DRC's Ebola response, said he was grateful for the support of international partners, who are working in an extremely difficult setting. "We can no longer say that Ebola virus disease is not curable."

In other outbreak developments, the DRC reported 38 more cases since Aug 9, lifting the outbreak total past 2,800 to 2,831.

https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs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Leadership

- Scientific Advisory Committee
- William H. Gates Sr.
- Warren Buffett

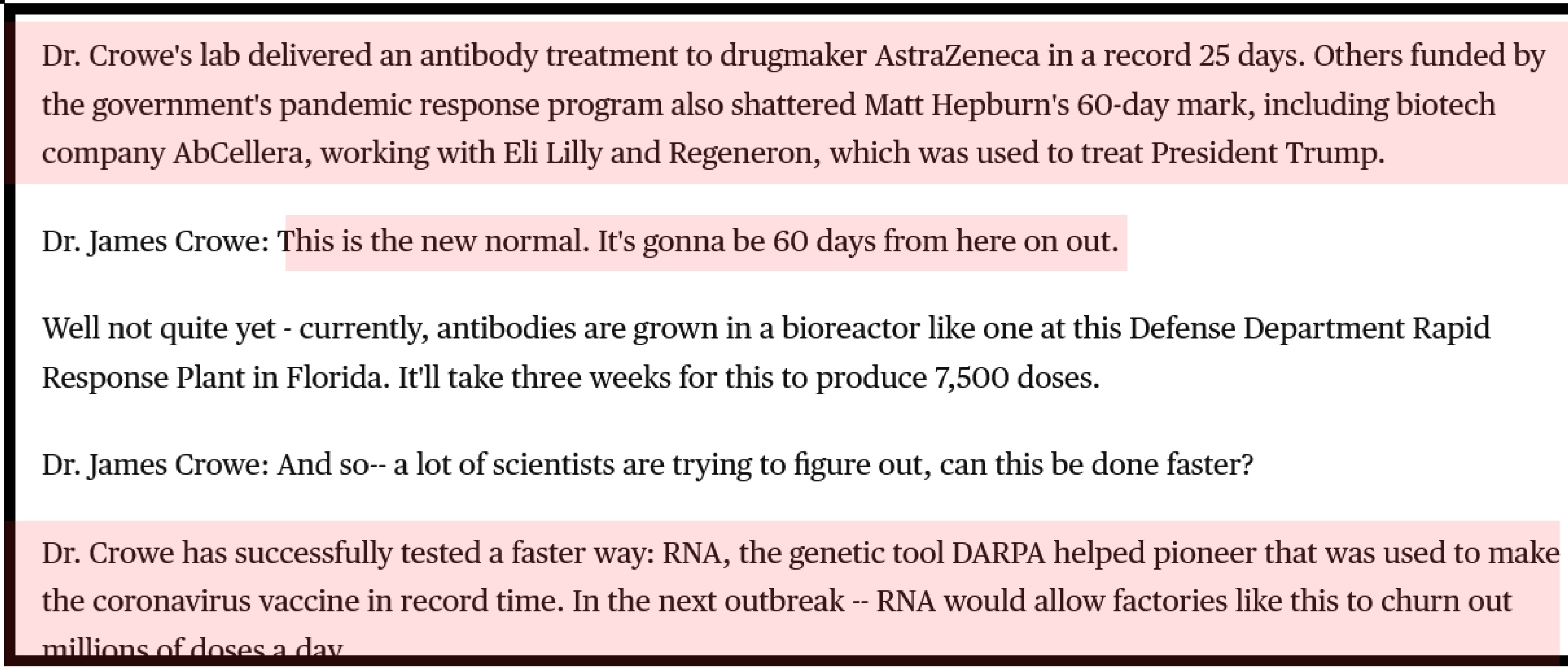
Dan Wattendorf

Director, Innovative Technology Solutions

WATTENDORF JOINED DARPA IN 2010
HE WAS A LEAD PROGENITOR OF THE MONOCLONAL
ANTIBODY PROGRAMS AT DARPA

HE NOW WORKS FOR THE BILL AND MELINDA GATES FOUNDATION

DR. JAMES CROWE



Dr. Crowe's lab delivered an antibody treatment to drugmaker AstraZeneca in a record 25 days. Others funded by the government's pandemic response program also shattered Matt Hepburn's 60-day mark, including biotech company AbCellera, working with Eli Lilly and Regeneron, which was used to treat President Trump.

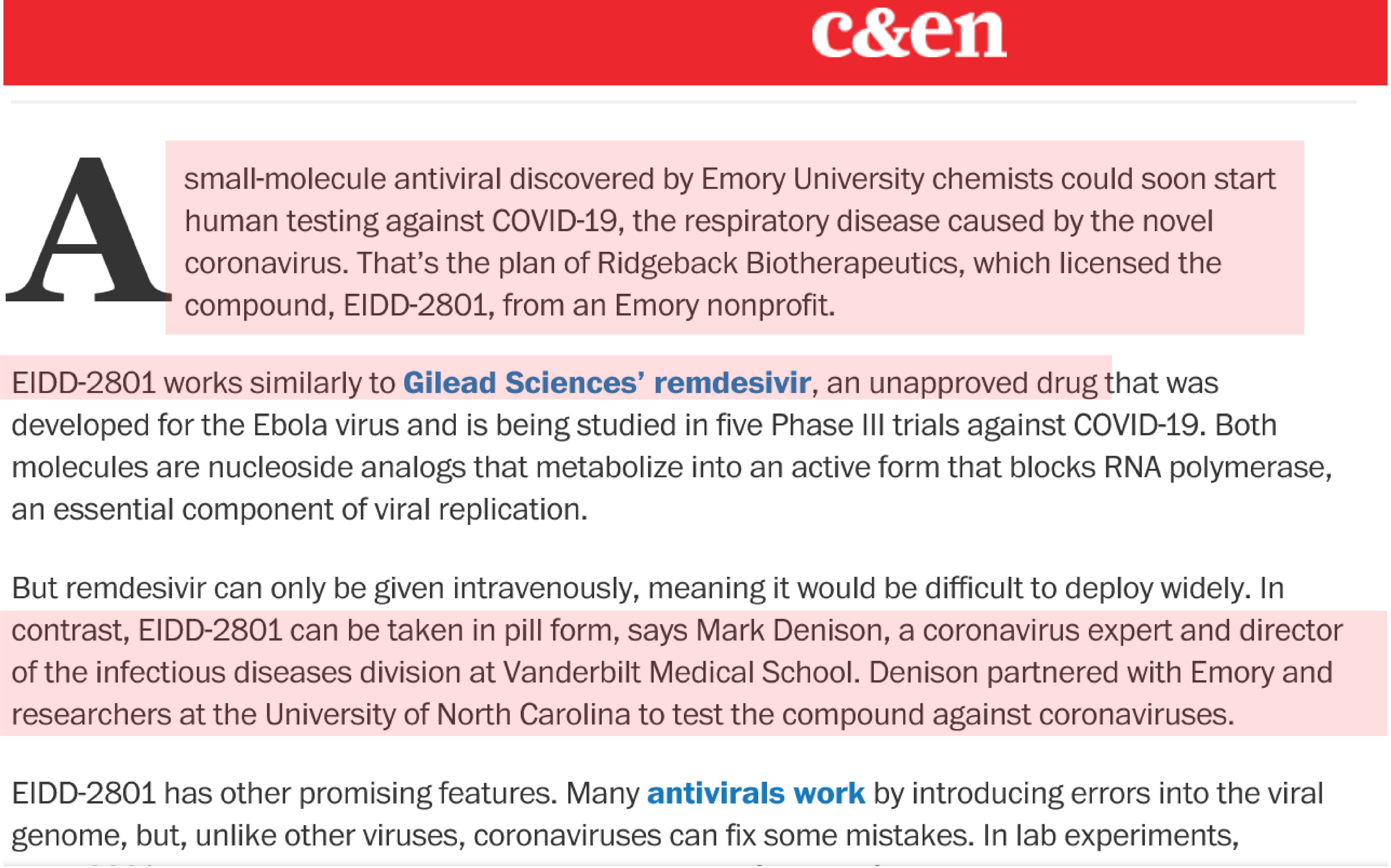
Dr. James Crowe: This is the new normal. It's gonna be 60 days from here on out.

Well not quite yet - currently, antibodies are grown in a bioreactor like one at this Defense Department Rapid Response Plant in Florida. It'll take three weeks for this to produce 7,500 doses.

Dr. James Crowe: And so-- a lot of scientists are trying to figure out, can this be done faster?

Dr. Crowe has successfully tested a faster way: RNA, the genetic tool DARPA helped pioneer that was used to make the coronavirus vaccine in record time. In the next outbreak -- RNA would allow factories like this to churn out millions of doses a day.

https://www.cbsnews.com/news/last-pandemic-science-military-60-minutes-2021-04-11/



c&en

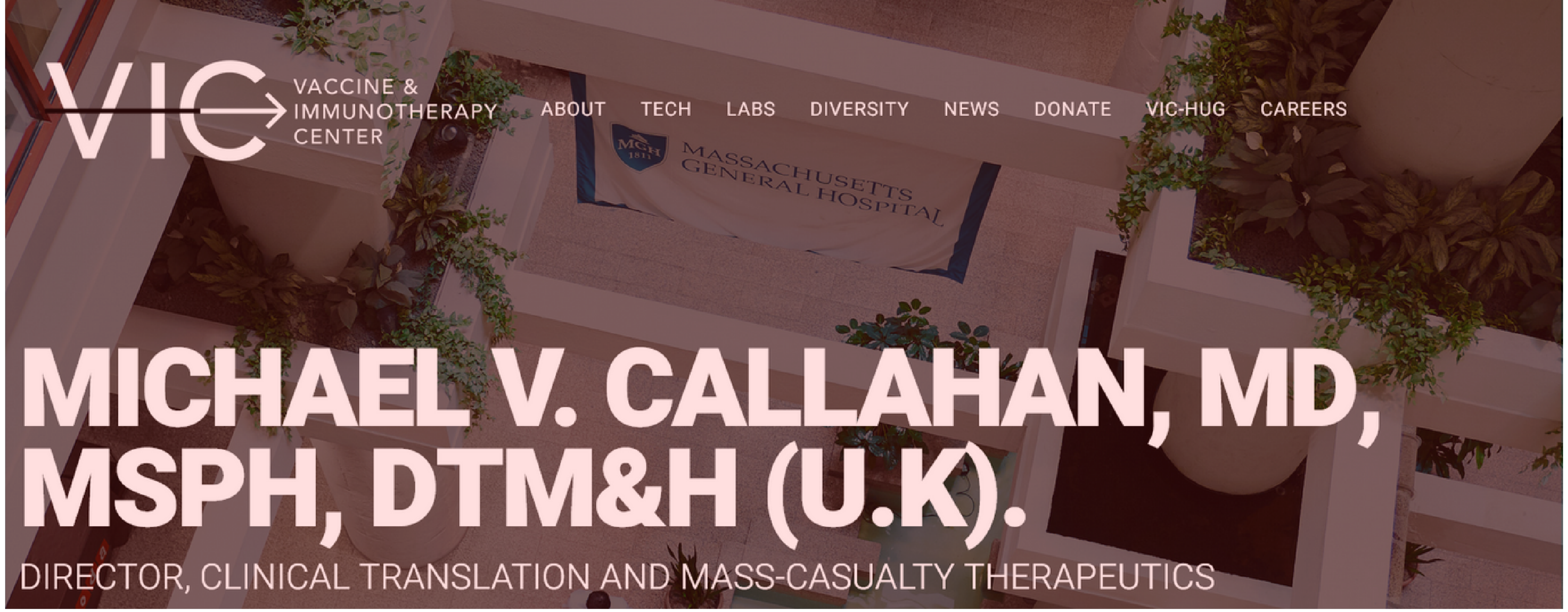
A small-molecule antiviral discovered by Emory University chemists could soon start human testing against COVID-19, the respiratory disease caused by the novel coronavirus. That’s the plan of Ridgeback Biotherapeutics, which licensed the compound, EIDD-2801, from an Emory nonprofit.

EIDD-2801 works similarly to **Gilead Sciences’ remdesivir**, an unapproved drug that was developed for the Ebola virus and is being studied in five Phase III trials against COVID-19. Both molecules are nucleoside analogs that metabolize into an active form that blocks RNA polymerase, an essential component of viral replication.

But remdesivir can only be given intravenously, meaning it would be difficult to deploy widely. In contrast, EIDD-2801 can be taken in pill form, says Mark Denison, a coronavirus expert and director of the infectious diseases division at Vanderbilt Medical School. Denison partnered with Emory and researchers at the University of North Carolina to test the compound against coronaviruses.

EIDD-2801 has other promising features. Many **antivirals work** by introducing errors into the viral genome, but, unlike other viruses, coronaviruses can fix some mistakes. In lab experiments,

https://cen.acs.org/biological-chemistry/infectious-disease/Emory-discovered-antiviral-poised-COVID/98/i12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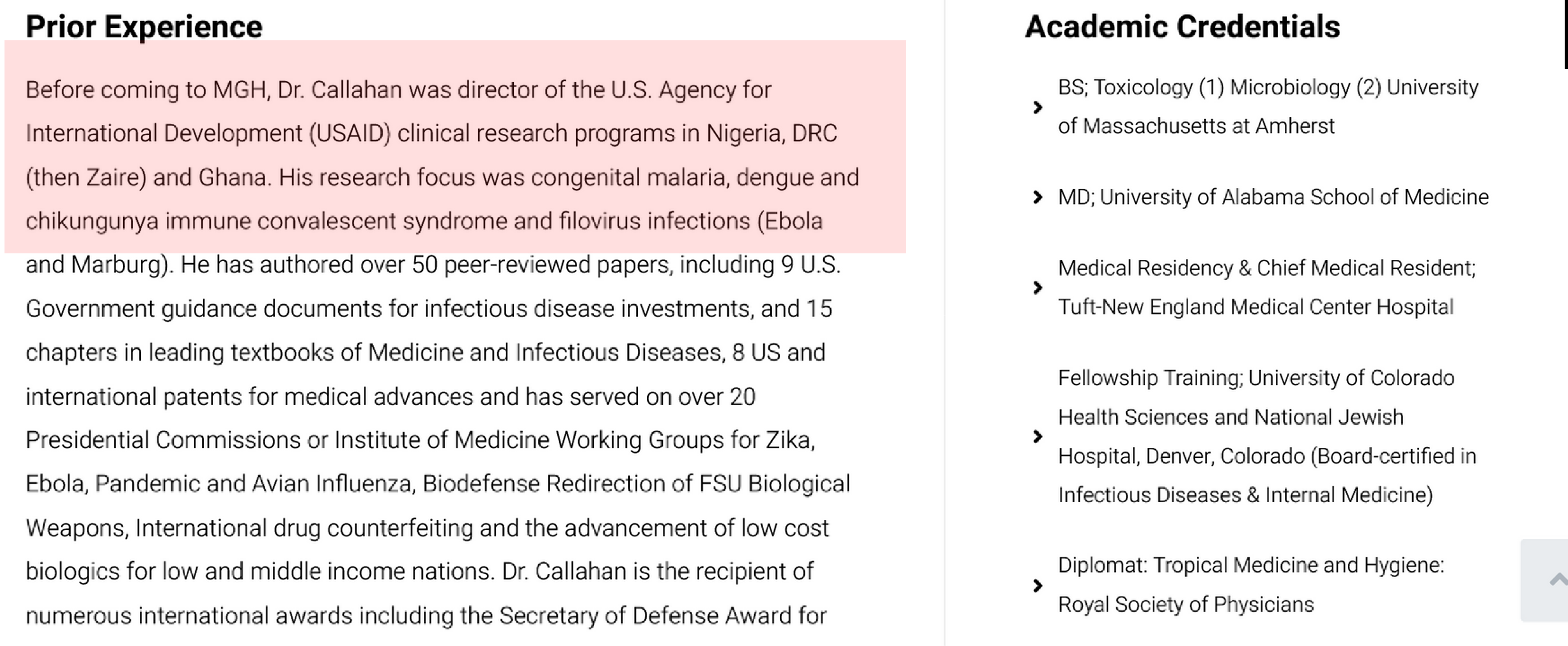
MICHAEL V. CALLAHAN, MD, MSPH, DTM&H (U.K).

DIRECTOR, CLINICAL TRANSLATION AND MASS-CASUALTY THERAPEUTICS

https://advancingcures.org/vic-management-michael-callahan/

MGH DIVISION OF INFECTIOUS DISEASE
Michael Callahan MD

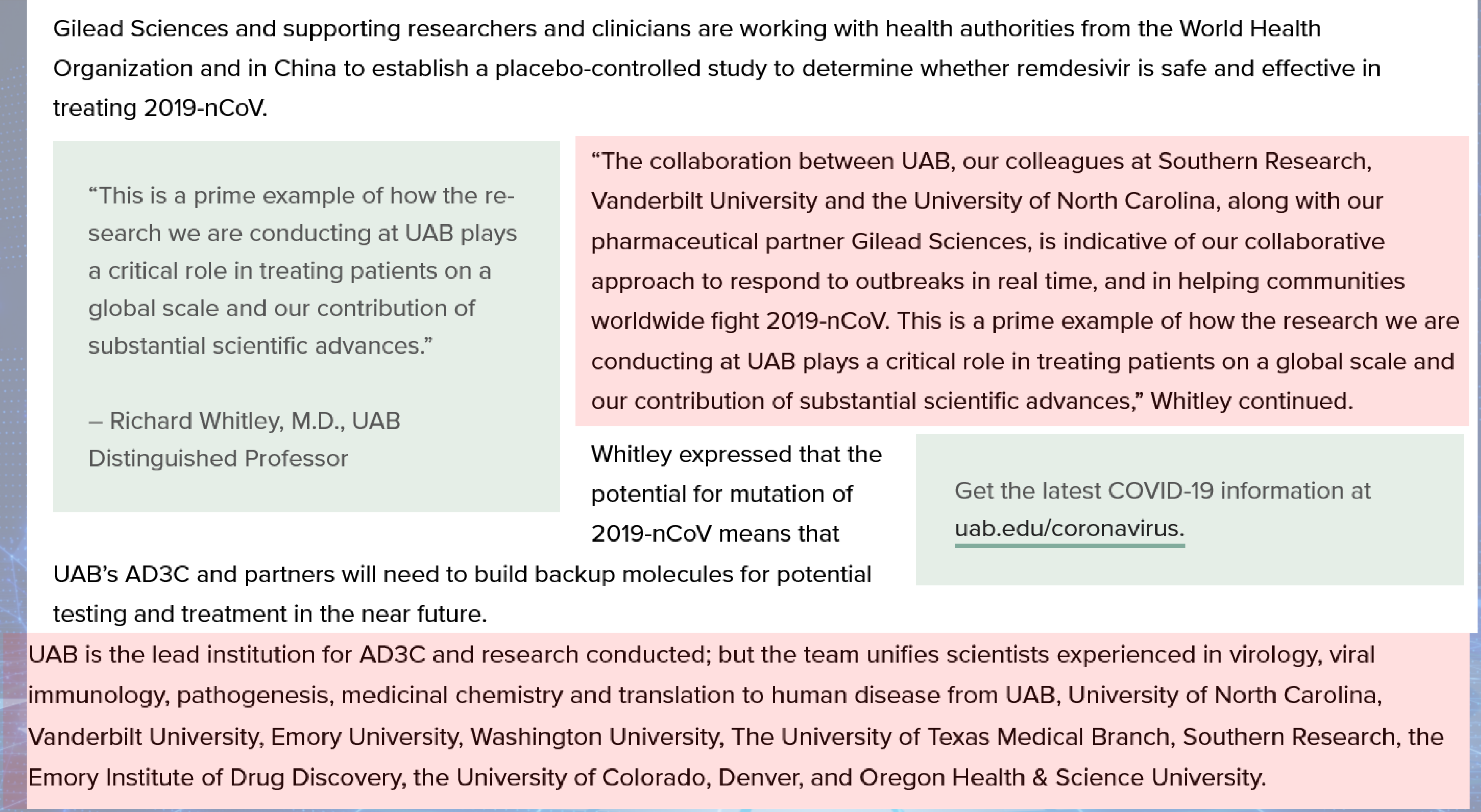


Prior Experience

Before coming to MGH, Dr. Callahan was director of the U.S. Agency for International Development (USAID) clinical research programs in Nigeria, DRC (then Zaire) and Ghana. His research focus was congenital malaria, dengue and chikungunya immune convalescent syndrome and filovirus infections (Ebola and Marburg). He has authored over 50 peer-reviewed papers, including 9 U.S. Government guidance documents for infectious disease investments, and 15 chapters in leading textbooks of Medicine and Infectious Diseases, 8 US and international patents for medical advances and has served on over 20 Presidential Commissions or Institute of Medicine Working Groups for Zika, Ebola, Pandemic and Avian Influenza, Biodefense Redirection of FSU Biological Weapons, International drug counterfeiting and the advancement of low cost biologics for low and middle income nations. Dr. Callahan is the recipient of numerous international awards including the Secretary of Defense Award for

Academic Credentials

- BS; Toxicology (1) Microbiology (2) University of Massachusetts at Amherst
- MD; University of Alabama School of Medicine
- Medical Residency & Chief Medical Resident; Tuft-New England Medical Center Hospital
- Fellowship Training; University of Colorado Health Sciences and National Jewish Hospital, Denver, Colorado (Board-certified in Infectious Diseases & Internal Medicine)
- Diplomat: Tropical Medicine and Hygiene: Royal Society of Physicians



Gilead Sciences and supporting researchers and clinicians are working with health authorities from the World Health Organization and in China to establish a placebo-controlled study to determine whether remdesivir is safe and effective in treating 2019-nCoV.

> “This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances.”
>
> – Richard Whitley, M.D., UAB Distinguished Professor

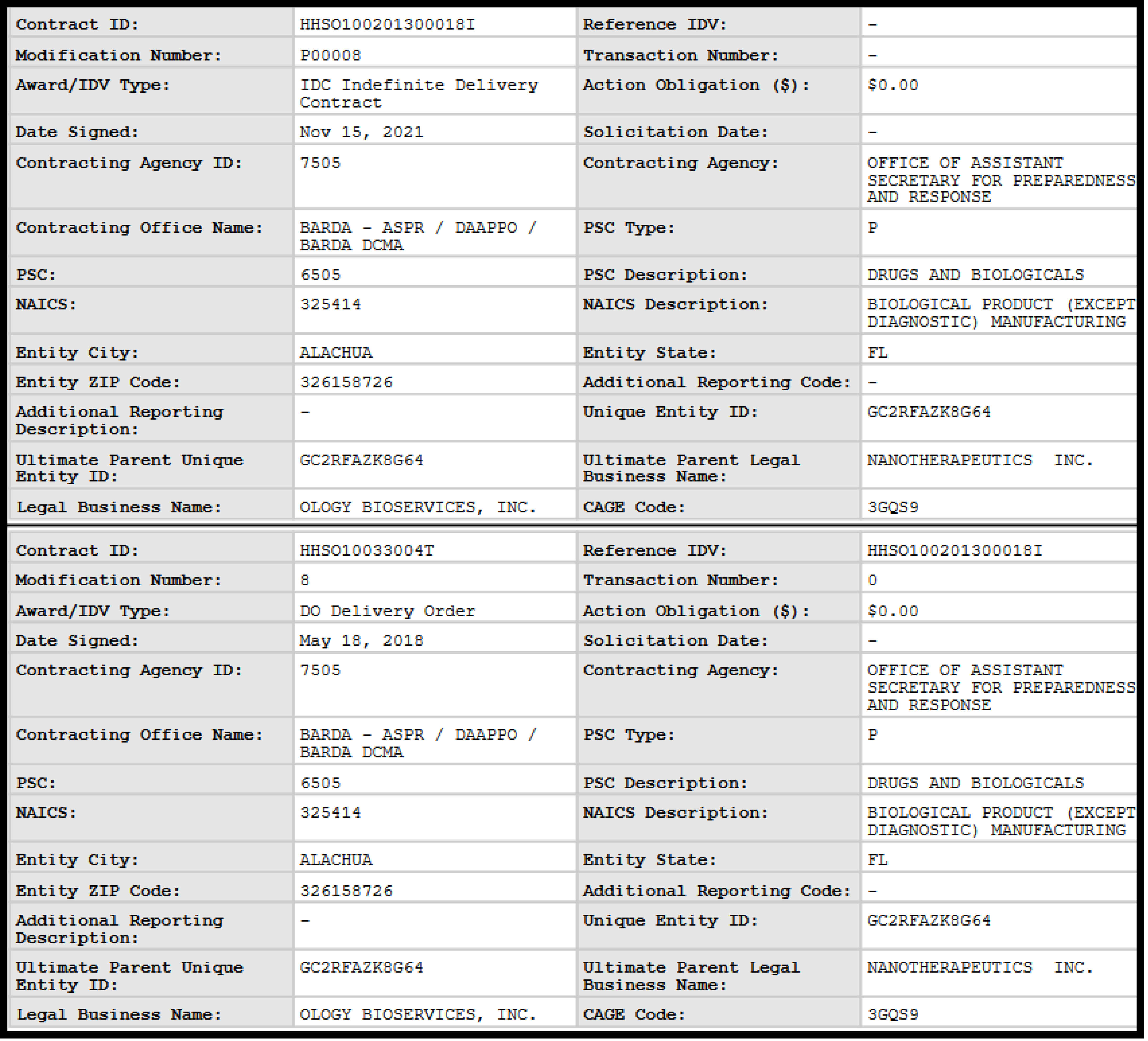
“The collaboration between UAB, our colleagues at Southern Research, Vanderbilt University and the University of North Carolina, along with our pharmaceutical partner Gilead Sciences, is indicative of our collaborative approach to respond to outbreaks in real time, and in helping communities worldwide fight 2019-nCoV. This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances,” Whitley continued.

Get the latest COVID-19 information at uab.edu/coronavirus.

Whitley expressed that the potential for mutation of 2019-nCoV means that UAB’s AD3C and partners will need to build backup molecules for potential testing and treatment in the near future.

UAB is the lead institution for AD3C and research conducted; but the team unifies scientists experienced in virology, viral immunology, pathogenesis, medicinal chemistry and translation to human disease from UAB, University of North Carolina, Vanderbilt University, Emory University, Washington University, The University of Texas Medical Branch, Southern Research, the Emory Institute of Drug Discovery, the University of Colorado, Denver, and Oregon Health & Science University.

HTTPS://WWW.UAB.EDU/NEWS/HEALTH/ITEM/11082-INVESTIGATIONAL-COMPOUND-REMDESIVIR-DEVELOPED-BY-UAB-AND-NIH-RESEARCHERS-BEING-USED-FOR-TREATMENT-OF-NOVEL-CORONAVIRUS



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Award/IDV Type:	IDC Indefinite Delivery Contract	**Action Obligation ($):**	$0.00
Date Signed:	Nov 15, 2021	**Solicitation Date:**	-
Contracting Agency ID:	7505	**Contracting Agency:**	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	**PSC Type:**	P
PSC:	6505	**PSC Description:**	DRUGS AND BIOLOGICALS
NAICS:	325414	**NAICS Description:**	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	**Entity State:**	FL
Entity ZIP Code:	326158726	**Additional Reporting Code:**	-
Additional Reporting Description:	-	**Unique Entity ID:**	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	**Ultimate Parent Legal Business Name:**	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	**CAGE Code:**	3GQS9

Contract ID:	HHSO10033004T	**Reference IDV:**	HHSO100201300018I
Modification Number:	8	**Transaction Number:**	0
Award/IDV Type:	DO Delivery Order	**Action Obligation ($):**	$0.00
Date Signed:	May 18, 2018	**Solicitation Date:**	-
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Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	**PSC Type:**	P
PSC:	6505	**PSC Description:**	DRUGS AND BIOLOGICALS
NAICS:	325414	**NAICS Description:**	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	**Entity State:**	FL
Entity ZIP Code:	326158726	**Additional Reporting Code:**	-
Additional Reporting Description:	-	**Unique Entity ID:**	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	**Ultimate Parent Legal Business Name:**	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	**CAGE Code:**	3GQS9

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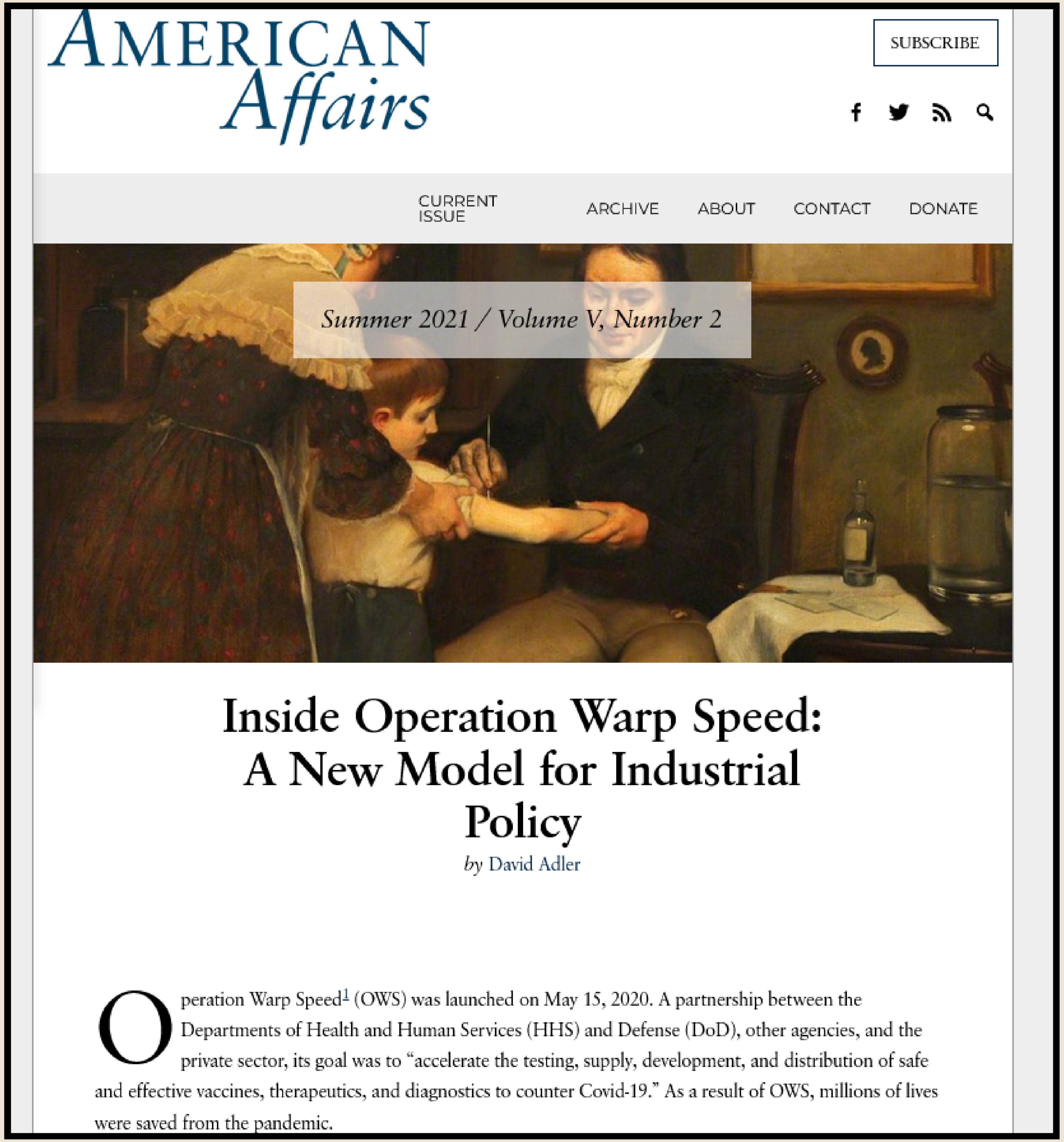
s=ICD&indexName=awardfull&templateName=PDF&q=UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+INC.%22+UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+IN



Summer 2021 / Volume V, Number 2

Inside Operation Warp Speed: A New Model for Industrial Policy

by David Adler

Operation Warp Speed[1] (OWS) was launched on May 15, 2020. A partnership between the Departments of Health and Human Services (HHS) and Defense (DoD), other agencies, and the private sector, its goal was to “accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter Covid-19.” As a result of OWS, millions of lives were saved from the pandemic.

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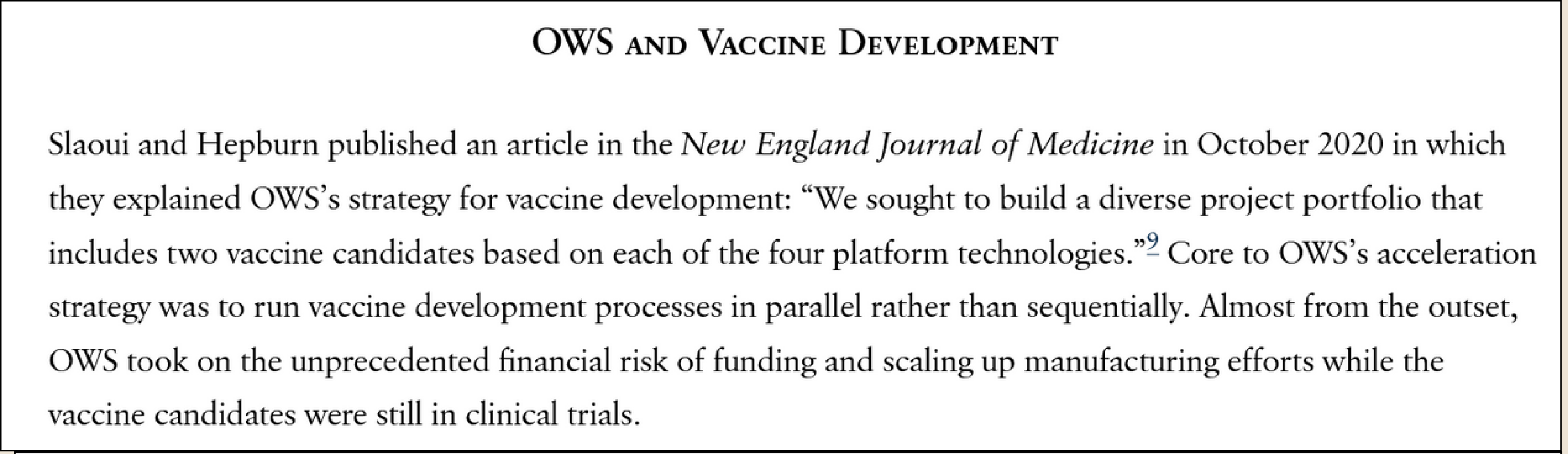
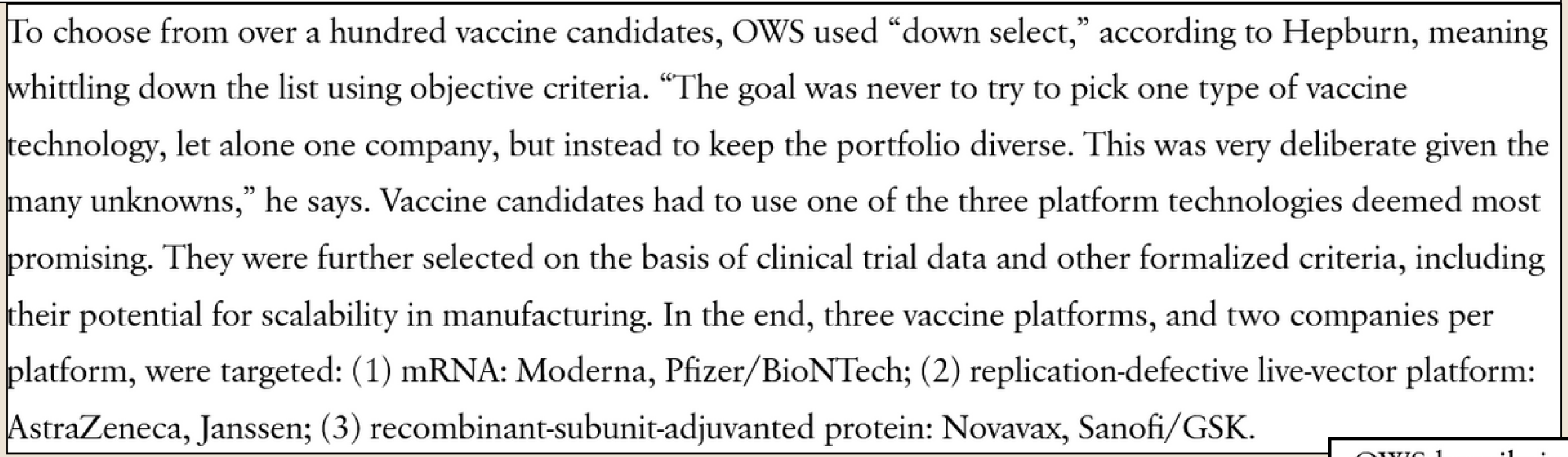
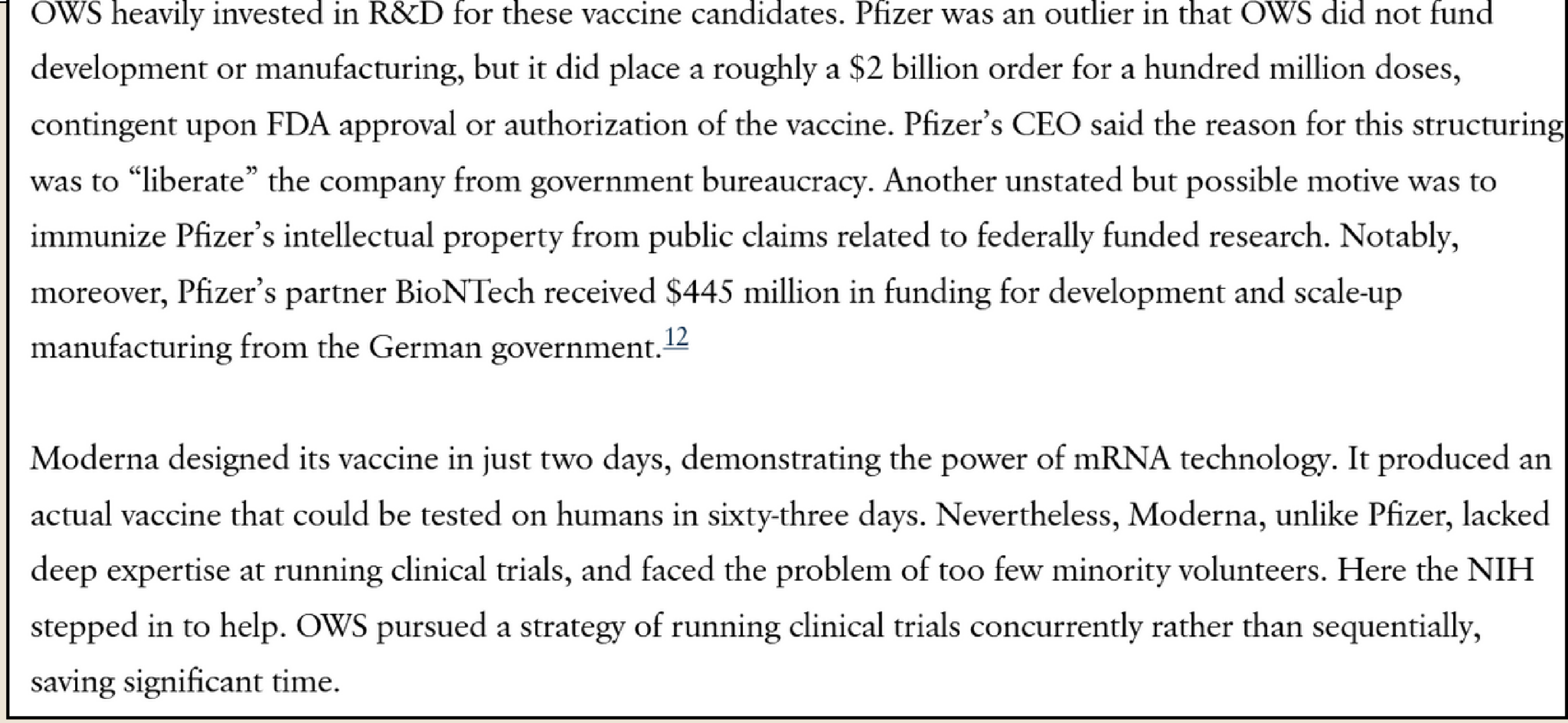


OWS and Vaccine Development

Slaoui and Hepburn published an article in the *New England Journal of Medicine* in October 2020 in which they explained OWS's strategy for vaccine development: "We sought to build a diverse project portfolio that includes two vaccine candidates based on each of the four platform technologies."[9] Core to OWS's acceleration strategy was to run vaccine development processes in parallel rather than sequentially. Almost from the outset, OWS took on the unprecedented financial risk of funding and scaling up manufacturing efforts while the vaccine candidates were still in clinical trials.



To choose from over a hundred vaccine candidates, OWS used "down select," according to Hepburn, meaning whittling down the list using objective criteria. "The goal was never to try to pick one type of vaccine technology, let alone one company, but instead to keep the portfolio diverse. This was very deliberate given the many unknowns," he says. Vaccine candidates had to use one of the three platform technologies deemed most promising. They were further selected on the basis of clinical trial data and other formalized criteria, including their potential for scalability in manufacturing. In the end, three vaccine platforms, and two companies per platform, were targeted: (1) mRNA: Moderna, Pfizer/BioNTech; (2) replication-defective live-vector platform: AstraZeneca, Janssen; (3) recombinant-subunit-adjuvanted protein: Novavax, Sanofi/GSK.



OWS heavily invested in R&D for these vaccine candidates. Pfizer was an outlier in that OWS did not fund development or manufacturing, but it did place a roughly a $2 billion order for a hundred million doses, contingent upon FDA approval or authorization of the vaccine. Pfizer's CEO said the reason for this structuring was to "liberate" the company from government bureaucracy. Another unstated but possible motive was to immunize Pfizer's intellectual property from public claims related to federally funded research. Notably, moreover, Pfizer's partner BioNTech received $445 million in funding for development and scale-up manufacturing from the German government.[12]

Moderna designed its vaccine in just two days, demonstrating the power of mRNA technology. It produced an actual vaccine that could be tested on humans in sixty-three days. Nevertheless, Moderna, unlike Pfizer, lacked deep expertise at running clinical trials, and faced the problem of too few minority volunteers. Here the NIH stepped in to help. OWS pursued a strategy of running clinical trials concurrently rather than sequentially, saving significant time.

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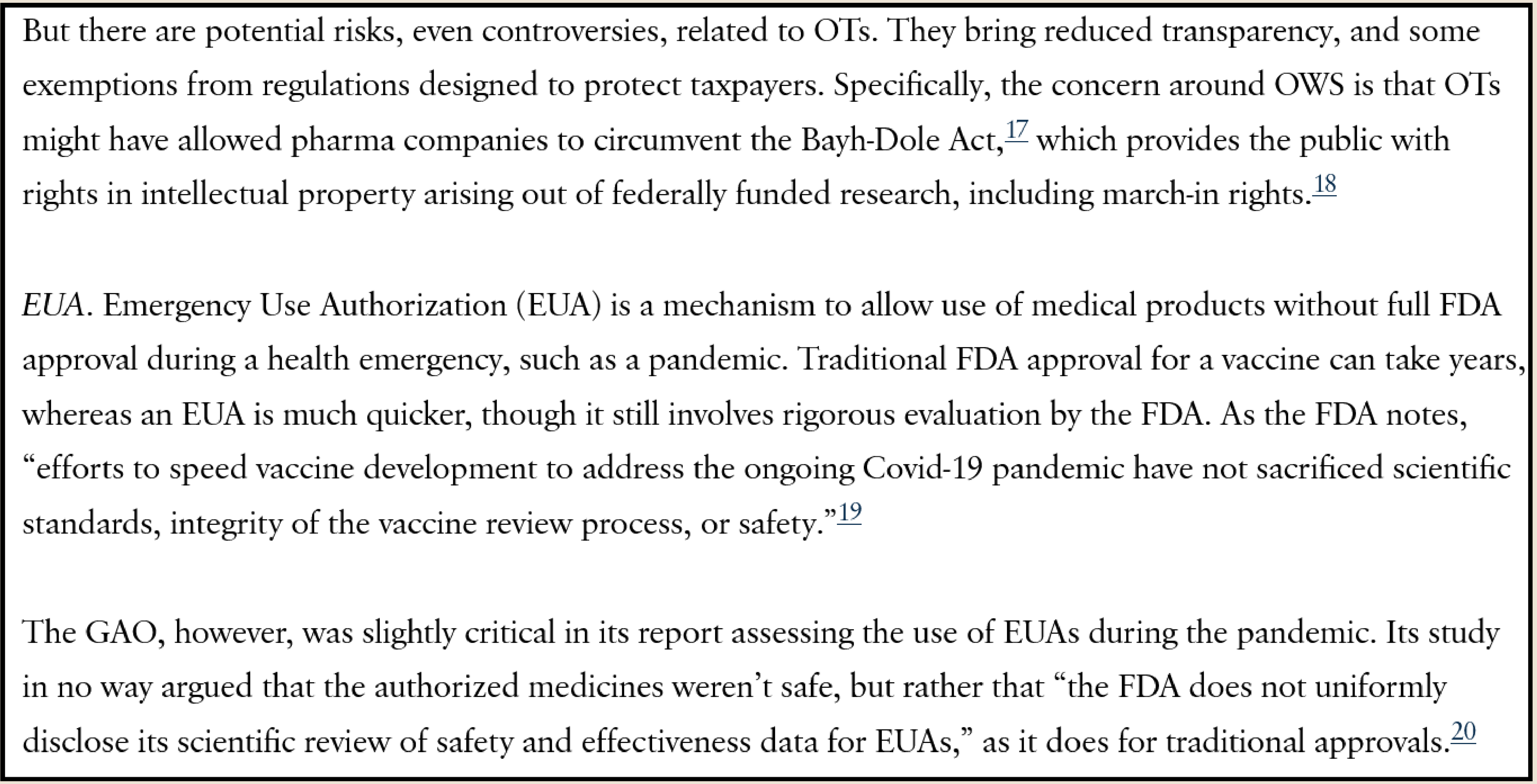
Dr. Michael Callahan, an infectious disease specialist at Massachusetts General Hospital and Harvard Medical School, explains just how radical these results were, including the novel technology and development efforts that led to them: “mRNA-based protein expression is the most recent interesting American invention,” Callahan says. “Warp Speed could not have happened if the technology had not been developed to move this quickly. We got very lucky with mRNA.” With mRNA, scientists only need to know the sequence of the virus to design a vaccine. Sequence data was provided by the Chinese in the first week of January 2020. China’s capabilities in this area are comparable to or better than America’s.

Callahan’s academic bio doesn’t convey the depth of his expertise. Callahan previously oversaw DARPA’s biodefense therapeutics portfolio, the “Accelerated Manufacture of Pharmaceuticals” (AMP) program, whose goal was to radically accelerate the manufacturing of protein vaccines, and sister programs “7 Day Biodefense” and “Prophecy” (to predict virus evolution). Callahan coled the world’s largest international medical evacuation from a hot zone, the repatriation of nearly four hundred Americans from the Covid-19-plagued *Diamond Princess* cruise ship, and emergency care of infected passengers on the *Grand Princess* cruise. He was then recruited as special adviser on Covid-19 to the assistant secretary of preparedness and response (ASPR), Robert Kadlec.



But there are potential risks, even controversies, related to OTs. They bring reduced transparency, and some exemptions from regulations designed to protect taxpayers. Specifically, the concern around OWS is that OTs might have allowed pharma companies to circumvent the Bayh-Dole Act,[17] which provides the public with rights in intellectual property arising out of federally funded research, including march-in rights.[18]

EUA. Emergency Use Authorization (EUA) is a mechanism to allow use of medical products without full FDA approval during a health emergency, such as a pandemic. Traditional FDA approval for a vaccine can take years, whereas an EUA is much quicker, though it still involves rigorous evaluation by the FDA. As the FDA notes, “efforts to speed vaccine development to address the ongoing Covid-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety.”[19]

The GAO, however, was slightly critical in its report assessing the use of EUAs during the pandemic. Its study in no way argued that the authorized medicines weren’t safe, but rather that “the FDA does not uniformly disclose its scientific review of safety and effectiveness data for EUAs,” as it does for traditional approvals.[20]

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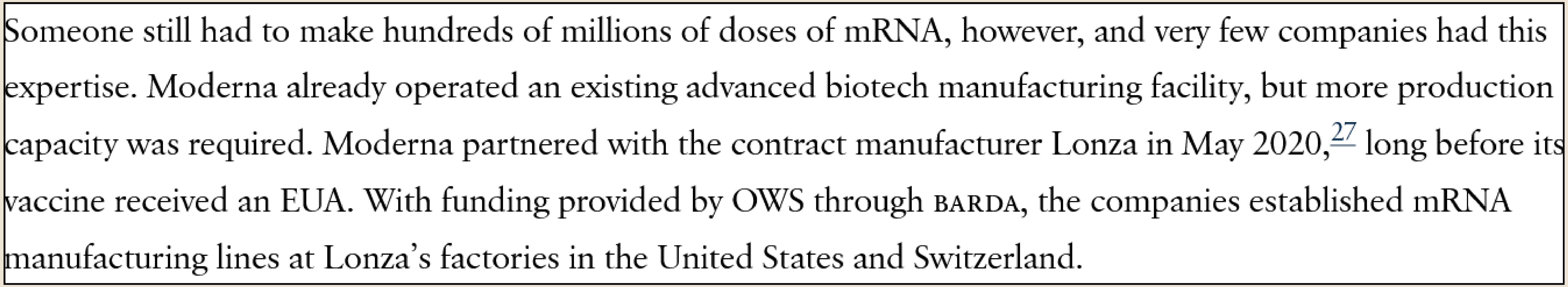

Someone still had to make hundreds of millions of doses of mRNA, however, and very few companies had this expertise. Moderna already operated an existing advanced biotech manufacturing facility, but more production capacity was required. Moderna partnered with the contract manufacturer Lonza in May 2020,[27] long before its vaccine received an EUA. With funding provided by OWS through BARDA, the companies established mRNA manufacturing lines at Lonza’s factories in the United States and Switzerland.

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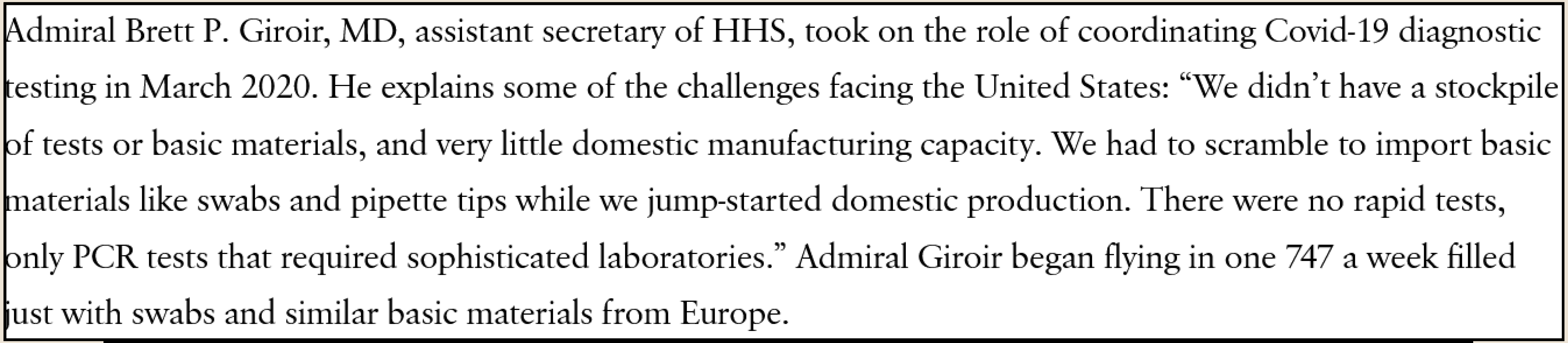
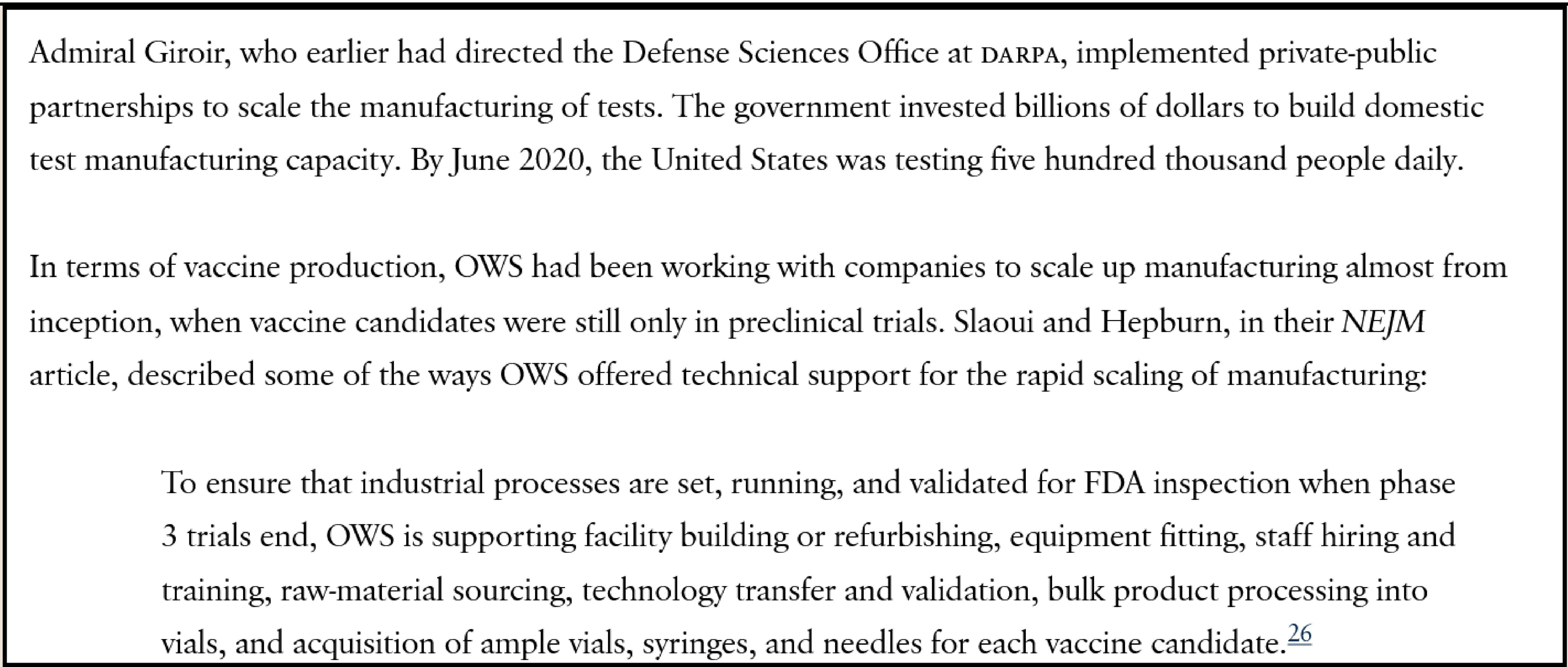


Admiral Brett P. Giroir, MD, assistant secretary of HHS, took on the role of coordinating Covid-19 diagnostic testing in March 2020. He explains some of the challenges facing the United States: “We didn’t have a stockpile of tests or basic materials, and very little domestic manufacturing capacity. We had to scramble to import basic materials like swabs and pipette tips while we jump-started domestic production. There were no rapid tests, only PCR tests that required sophisticated laboratories.” Admiral Giroir began flying in one 747 a week filled just with swabs and similar basic materials from Europe.



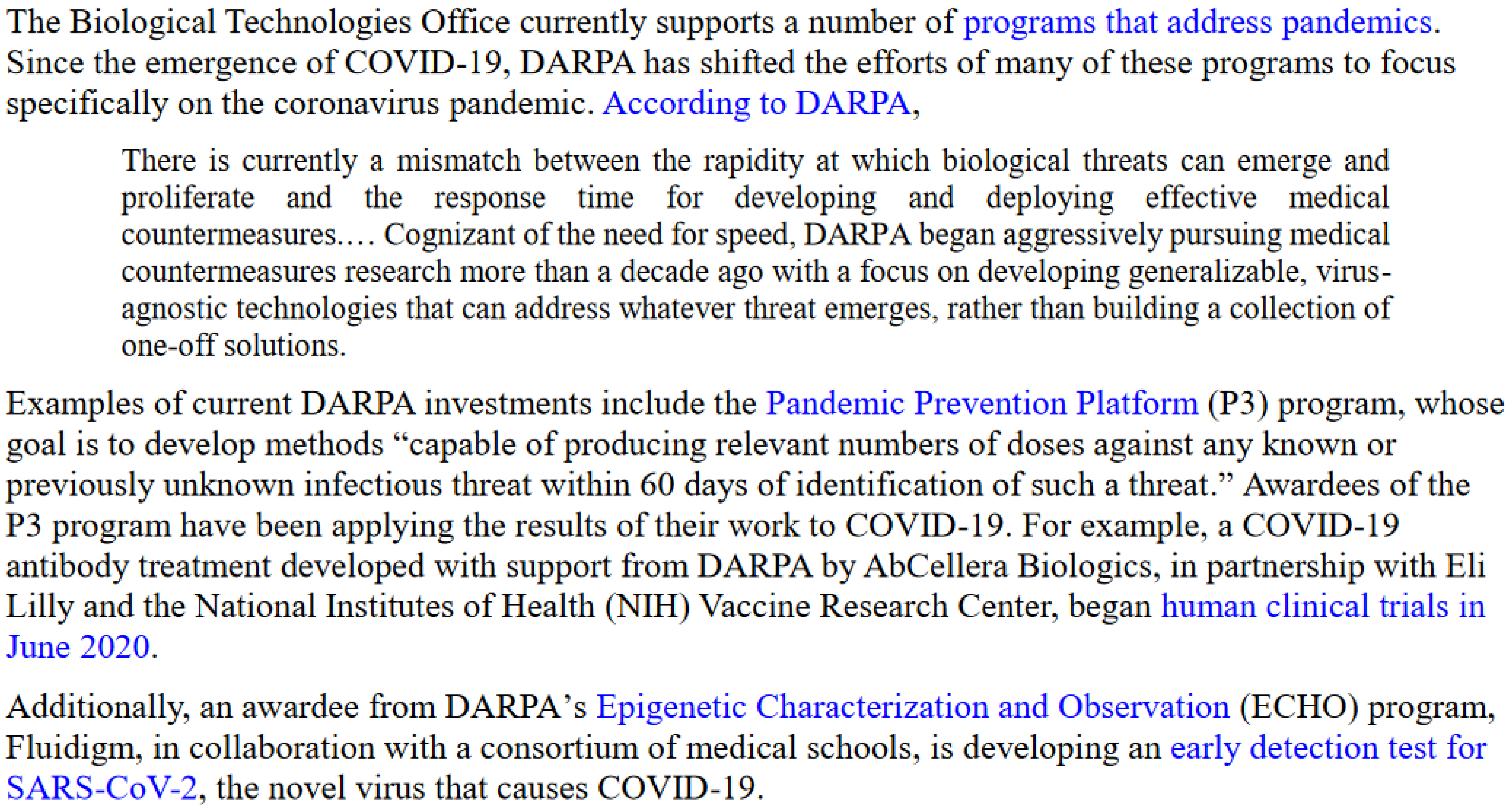
Admiral Giroir, who earlier had directed the Defense Sciences Office at DARPA, implemented private-public partnerships to scale the manufacturing of tests. The government invested billions of dollars to build domestic test manufacturing capacity. By June 2020, the United States was testing five hundred thousand people daily.

In terms of vaccine production, OWS had been working with companies to scale up manufacturing almost from inception, when vaccine candidates were still only in preclinical trials. Slaoui and Hepburn, in their *NEJM* article, described some of the ways OWS offered technical support for the rapid scaling of manufacturing:

> To ensure that industrial processes are set, running, and validated for FDA inspection when phase 3 trials end, OWS is supporting facility building or refurbishing, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate.[26]

Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.

These DARPA programs are part of a broader biodefense effort to address threats that include naturally occurring epidemics, as well as accidental biological exposures, biowarfare, and bioterrorism. The nation's biodefense enterprise is distributed, spanning multiple departments and agencies with different missions, making preparing for and responding to a diverse and evolving set of biological threats challenging. In 2016, Congress directed the Secretaries of Health and Human Services (HHS), Defense, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan (P.L. 114-328, Section 1086). Issued in September 2018, the *National Biodefense Strategy* (with an implementation plan in Annex I) calls for the integration of biodefense R&D into federal planning, emphasizing the development of procedures and policies for interagency coordination of R&D efforts associated with responding to a biological incident. While the plan also calls for the sustainment of a robust national science and technology base to support biodefense, it does not articulate a need for interagency R&D planning and coordination. In 2015, the Blue Ribbon Study Panel on Biodefense, now the Bipartisan Commission on Biodefense, highlighted military-civilian collaboration in biological R&D as one of many issues that "deserve more congressional oversight."



The Biological Technologies Office currently supports a number of programs that address pandemics. Since the emergence of COVID-19, DARPA has shifted the efforts of many of these programs to focus specifically on the coronavirus pandemic. According to DARPA,

> There is currently a mismatch between the rapidity at which biological threats can emerge and proliferate and the response time for developing and deploying effective medical countermeasures.… Cognizant of the need for speed, DARPA began aggressively pursuing medical countermeasures research more than a decade ago with a focus on developing generalizable, virus-agnostic technologies that can address whatever threat emerges, rather than building a collection of one-off solutions.

Examples of current DARPA investments include the Pandemic Prevention Platform (P3) program, whose goal is to develop methods "capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat." Awardees of the P3 program have been applying the results of their work to COVID-19. For example, a COVID-19 antibody treatment developed with support from DARPA by AbCellera Biologics, in partnership with Eli Lilly and the National Institutes of Health (NIH) Vaccine Research Center, began human clinical trials in June 2020.

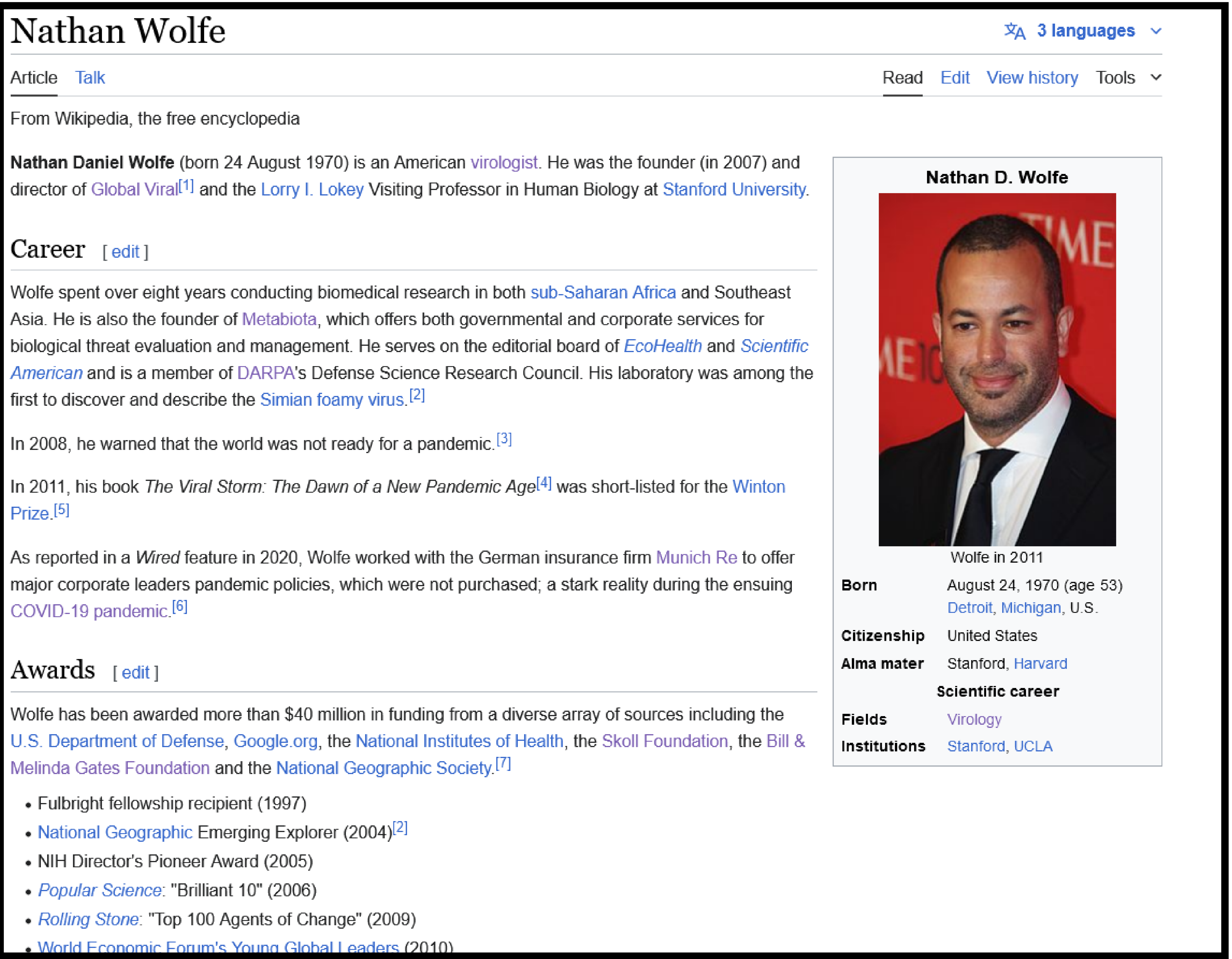
Additionally, an awardee from DARPA's Epigenetic Characterization and Observation (ECHO) program, Fluidigm, in collaboration with a consortium of medical schools, is developing an early detection test for SARS-CoV-2, the novel virus that causes COVID-19.

In its role as advisor to the Secretary of HHS, the National Biodefense Science Board (NBSB), stated that

> R&D for technologies, platforms, and systems to develop new MCM [medical countermeasures] against Disease X in 28 days from the recognition of the outbreak, which NBSB recommends as [a]

Nathan Wolfe-

Ecohealth Alliance Collaborator with DARPA



Nathan Wolfe

From Wikipedia, the free encyclopedia

Nathan Daniel Wolfe (born 24 August 1970) is an American virologist. He was the founder (in 2007) and director of Global Viral[1] and the Lorry I. Lokey Visiting Professor in Human Biology at Stanford University.

Career [edit]

Wolfe spent over eight years conducting biomedical research in both sub-Saharan Africa and Southeast Asia. He is also the founder of Metabiota, which offers both governmental and corporate services for biological threat evaluation and management. He serves on the editorial board of *EcoHealth* and *Scientific American* and is a member of DARPA's Defense Science Research Council. His laboratory was among the first to discover and describe the Simian foamy virus.[2]

In 2008, he warned that the world was not ready for a pandemic.[3]

In 2011, his book *The Viral Storm: The Dawn of a New Pandemic Age*[4] was short-listed for the Winton Prize.[5]

As reported in a *Wired* feature in 2020, Wolfe worked with the German insurance firm Munich Re to offer major corporate leaders pandemic policies, which were not purchased; a stark reality during the ensuing COVID-19 pandemic.[6]

Awards [edit]

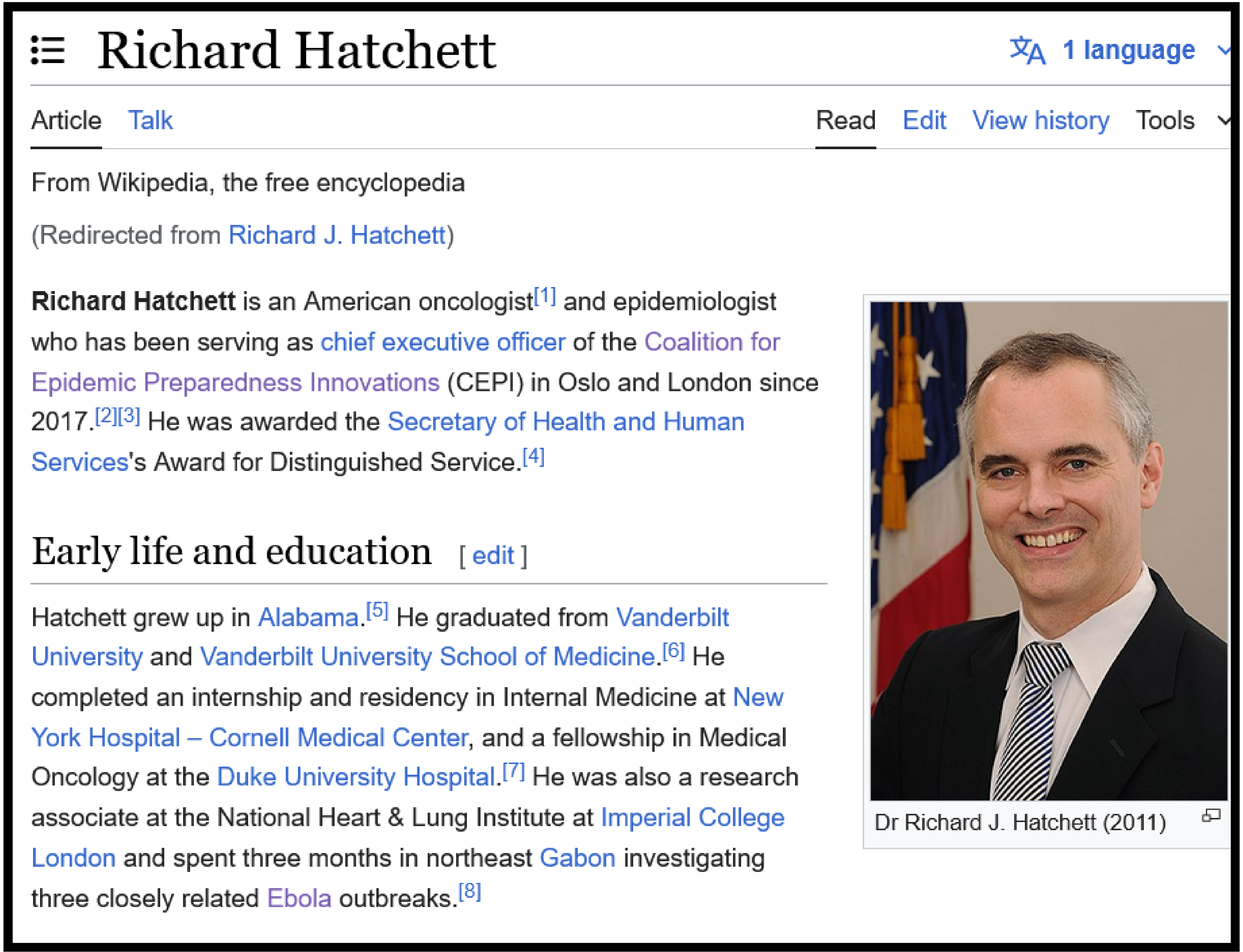
Wolfe has been awarded more than $40 million in funding from a diverse array of sources including the U.S. Department of Defense, Google.org, the National Institutes of Health, the Skoll Foundation, the Bill & Melinda Gates Foundation and the National Geographic Society.[7]

- Fulbright fellowship recipient (1997)
- National Geographic Emerging Explorer (2004)[2]
- NIH Director's Pioneer Award (2005)
- *Popular Science*: "Brilliant 10" (2006)
- *Rolling Stone*: "Top 100 Agents of Change" (2009)
- World Economic Forum's Young Global Leaders (2010)

Nathan D. Wolfe

Wolfe in 2011

Born	August 24, 1970 (age 53) Detroit, Michigan, U.S.
Citizenship	United States
Alma mater	Stanford, Harvard
Scientific career	
Fields	Virology
Institutions	Stanford, UCLA



Richard Hatchett

From Wikipedia, the free encyclopedia

(Redirected from Richard J. Hatchett)

Richard Hatchett is an American oncologist[1] and epidemiologist who has been serving as chief executive officer of the Coalition for Epidemic Preparedness Innovations (CEPI) in Oslo and London since 2017.[2][3] He was awarded the Secretary of Health and Human Services's Award for Distinguished Service.[4]

Dr Richard J. Hatchett (2011)

Early life and education

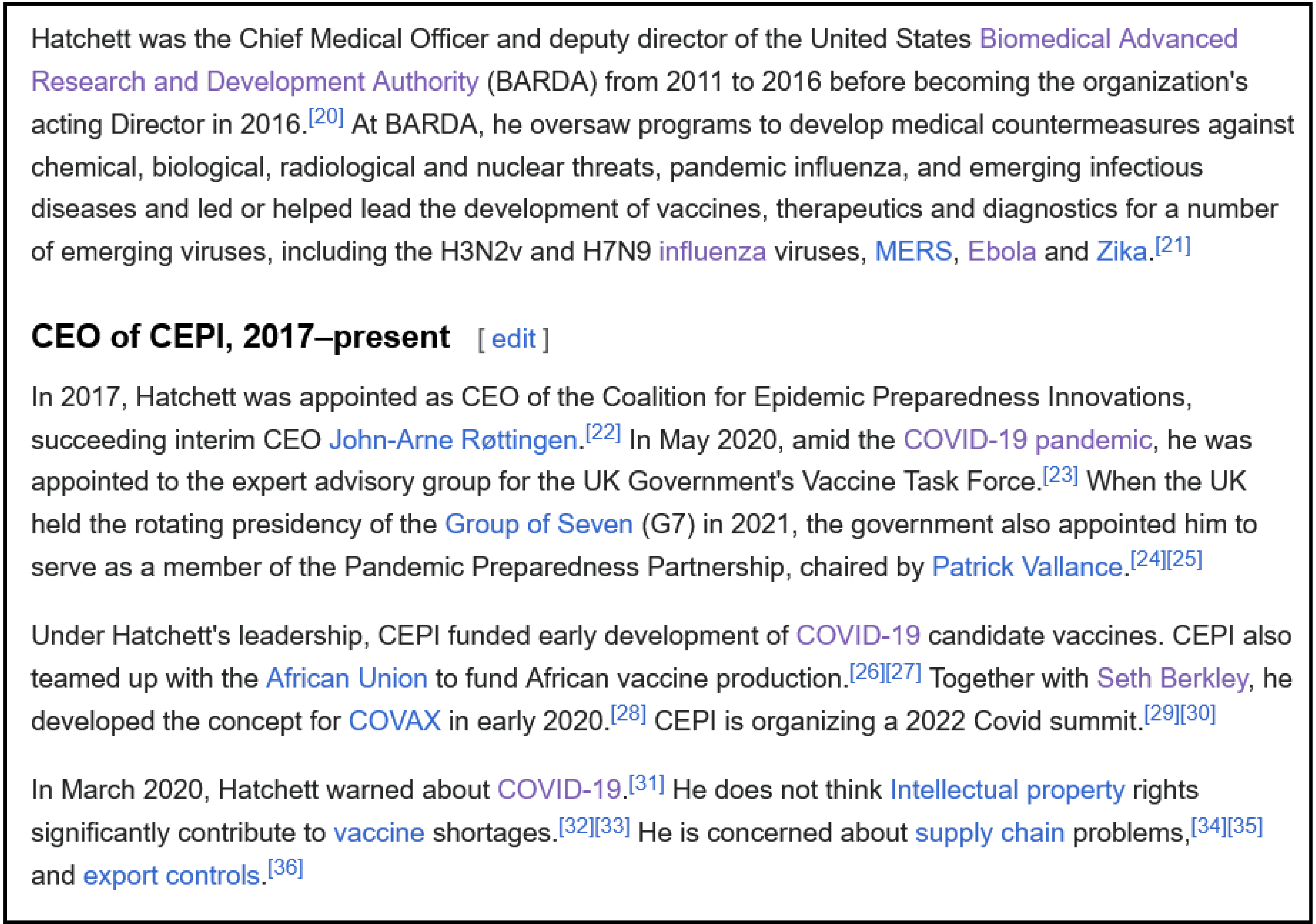
[edit]

Hatchett grew up in Alabama.[5] He graduated from Vanderbilt University and Vanderbilt University School of Medicine.[6] He completed an internship and residency in Internal Medicine at New York Hospital – Cornell Medical Center, and a fellowship in Medical Oncology at the Duke University Hospital.[7] He was also a research associate at the National Heart & Lung Institute at Imperial College London and spent three months in northeast Gabon investigating three closely related Ebola outbreaks.[8]

Richard Hatchett:

Vanderbilt Univ,
Cornell, & Duke

Suspected Former CIA
Former BARDA
Current CEO at CEPI



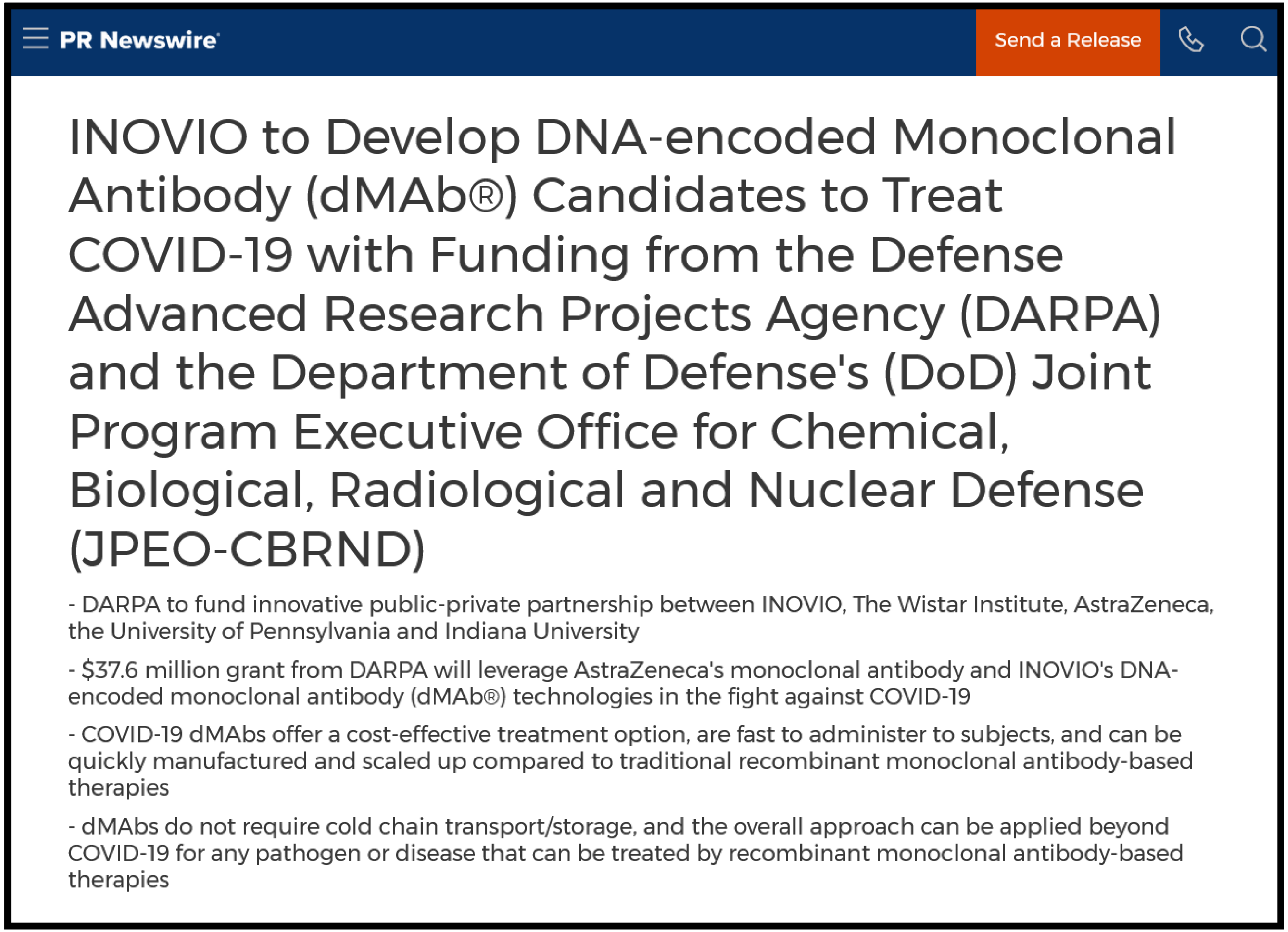
Hatchett was the Chief Medical Officer and deputy director of the United States Biomedical Advanced Research and Development Authority (BARDA) from 2011 to 2016 before becoming the organization's acting Director in 2016.[20] At BARDA, he oversaw programs to develop medical countermeasures against chemical, biological, radiological and nuclear threats, pandemic influenza, and emerging infectious diseases and led or helped lead the development of vaccines, therapeutics and diagnostics for a number of emerging viruses, including the H3N2v and H7N9 influenza viruses, MERS, Ebola and Zika.[21]

CEO of CEPI, 2017–present [edit]

In 2017, Hatchett was appointed as CEO of the Coalition for Epidemic Preparedness Innovations, succeeding interim CEO John-Arne Røttingen.[22] In May 2020, amid the COVID-19 pandemic, he was appointed to the expert advisory group for the UK Government's Vaccine Task Force.[23] When the UK held the rotating presidency of the Group of Seven (G7) in 2021, the government also appointed him to serve as a member of the Pandemic Preparedness Partnership, chaired by Patrick Vallance.[24][25]

Under Hatchett's leadership, CEPI funded early development of COVID-19 candidate vaccines. CEPI also teamed up with the African Union to fund African vaccine production.[26][27] Together with Seth Berkley, he developed the concept for COVAX in early 2020.[28] CEPI is organizing a 2022 Covid summit.[29][30]

In March 2020, Hatchett warned about COVID-19.[31] He does not think Intellectual property rights significantly contribute to vaccine shortages.[32][33] He is concerned about supply chain problems,[34][35] and export controls.[36]



INOVIO to Develop DNA-encoded Monoclonal Antibody (dMAb®) Candidates to Treat COVID-19 with Funding from the Defense Advanced Research Projects Agency (DARPA) and the Department of Defense's (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)

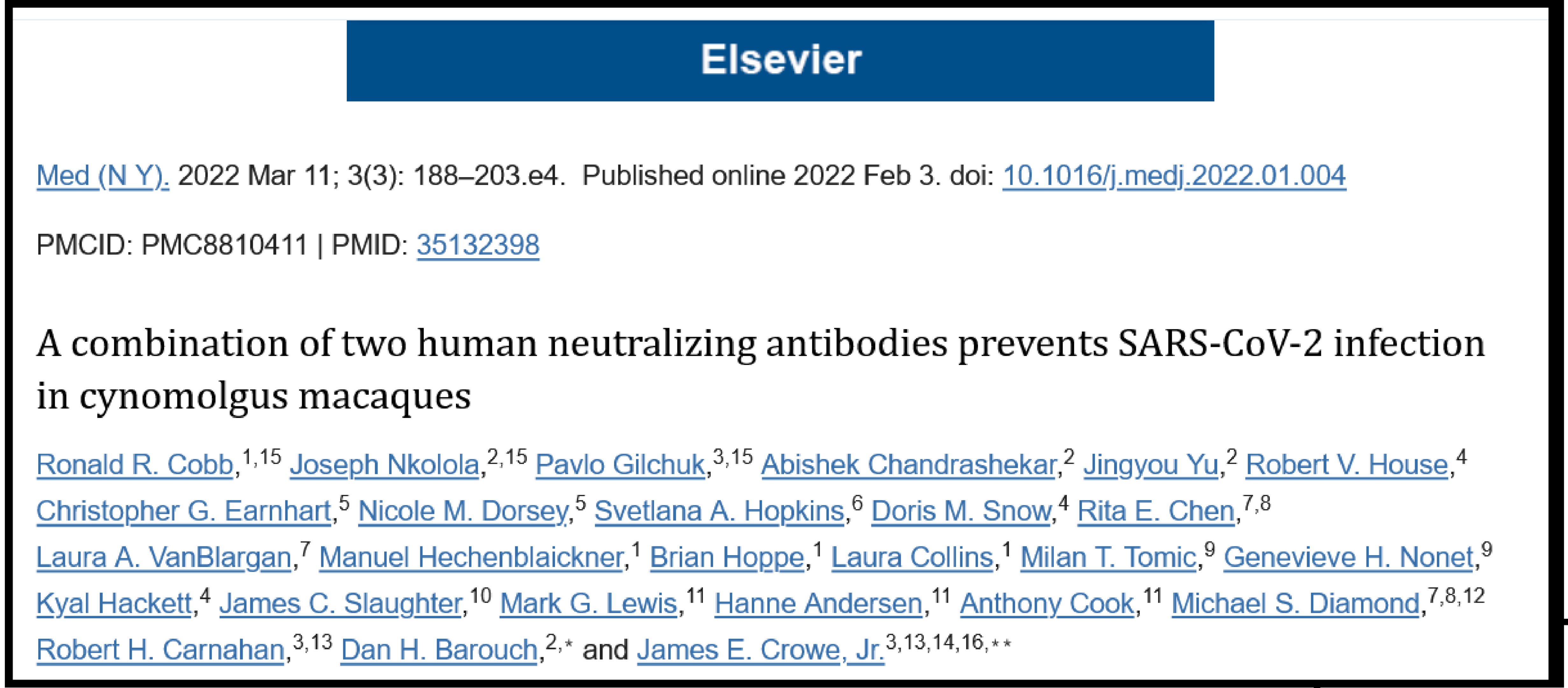
- DARPA to fund innovative public-private partnership between INOVIO, The Wistar Institute, AstraZeneca, the University of Pennsylvania and Indiana University

- $37.6 million grant from DARPA will leverage AstraZeneca's monoclonal antibody and INOVIO's DNA-encoded monoclonal antibody (dMAb®) technologies in the fight against COVID-19

- COVID-19 dMAbs offer a cost-effective treatment option, are fast to administer to subjects, and can be quickly manufactured and scaled up compared to traditional recombinant monoclonal antibody-based therapies

- dMAbs do not require cold chain transport/storage, and the overall approach can be applied beyond COVID-19 for any pathogen or disease that can be treated by recombinant monoclonal antibody-based therapies

mhttps://www.prnewswire.com/news-releases/inovio-to-develop-dna-encoded-monoclonal-antibody-dmab-candidates-to-treat-covid-19-with-funding-from-the-defense-advanced-research-projects-agency-darpa-and-the-department-of-defenses-dod-joint-program-executive-office-fo-301192706.html



Med (N Y). 2022 Mar 11; 3(3): 188–203.e4. Published online 2022 Feb 3. doi: 10.1016/j.medj.2022.01.004

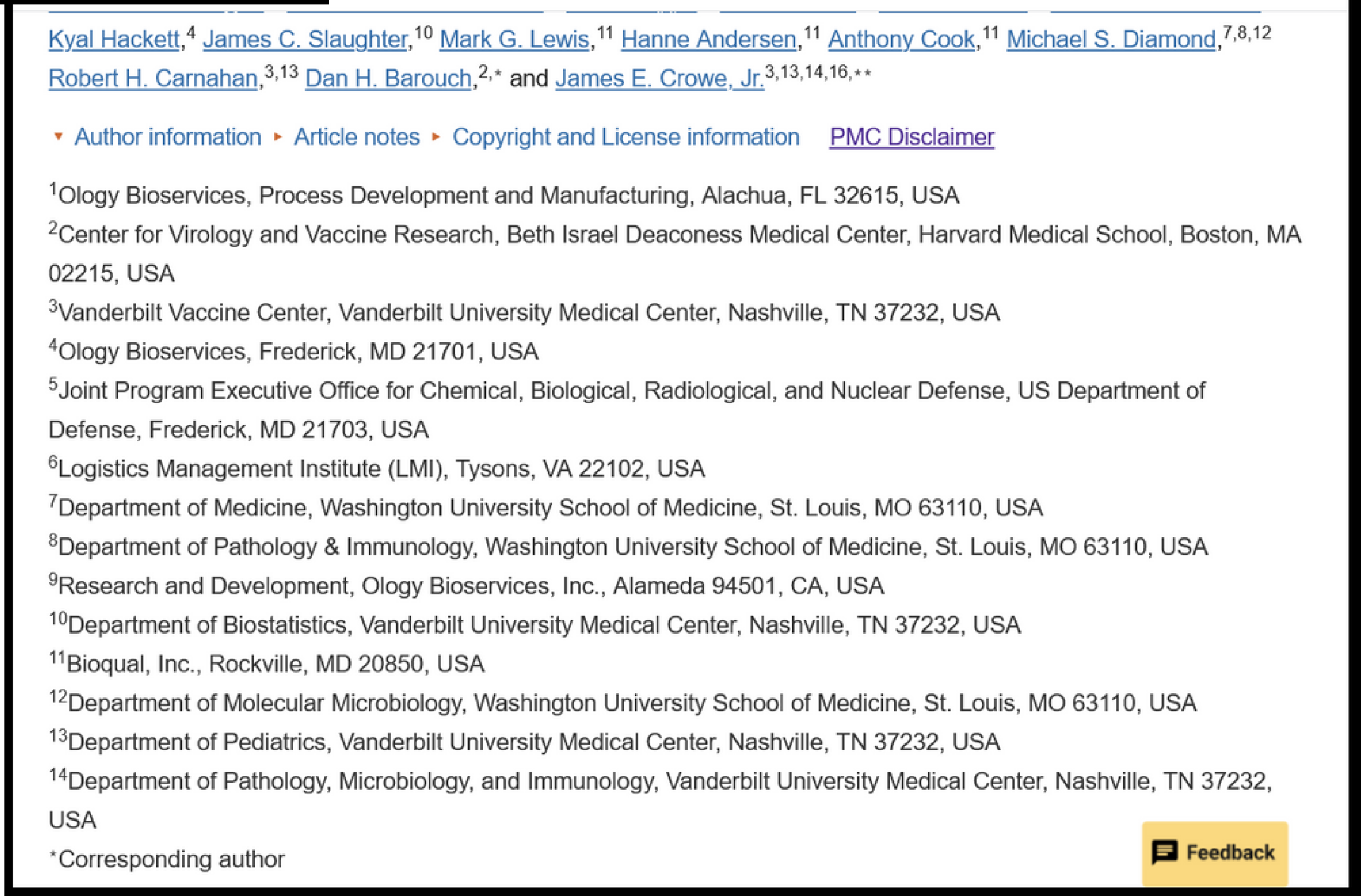
PMCID: PMC8810411 | PMID: 35132398

A combination of two human neutralizing antibodies prevents SARS-CoV-2 infection in cynomolgus macaques

Ronald R. Cobb,[1,15] Joseph Nkolola,[2,15] Pavlo Gilchuk,[3,15] Abishek Chandrashekar,[2] Jingyou Yu,[2] Robert V. House,[4] Christopher G. Earnhart,[5] Nicole M. Dorsey,[5] Svetlana A. Hopkins,[6] Doris M. Snow,[4] Rita E. Chen,[7,8] Laura A. VanBlargan,[7] Manuel Hechenblaickner,[1] Brian Hoppe,[1] Laura Collins,[1] Milan T. Tomic,[9] Genevieve H. Nonet,[9] Kyal Hackett,[4] James C. Slaughter,[10] Mark G. Lewis,[11] Hanne Andersen,[11] Anthony Cook,[11] Michael S. Diamond,[7,8,12] Robert H. Carnahan,[3,13] Dan H. Barouch,[2,*] and James E. Crowe, Jr.[3,13,14,16,**]

2022

Crowe of Vanderbilt alongside the JPEO-CBRND & Ology Bioservices



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[4] Ology Bioservices, Frederick, MD 21701, USA
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